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Fanton et al.

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(54) RING CINCH ASSEMBLY TO ATTACH BONE TO TISSUE

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- (*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 543 days.

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(65) Prior Publication Data

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(51) Int. Cl.

 $A61B\ 17/04$ (2006.01)

See application file for complete search history.

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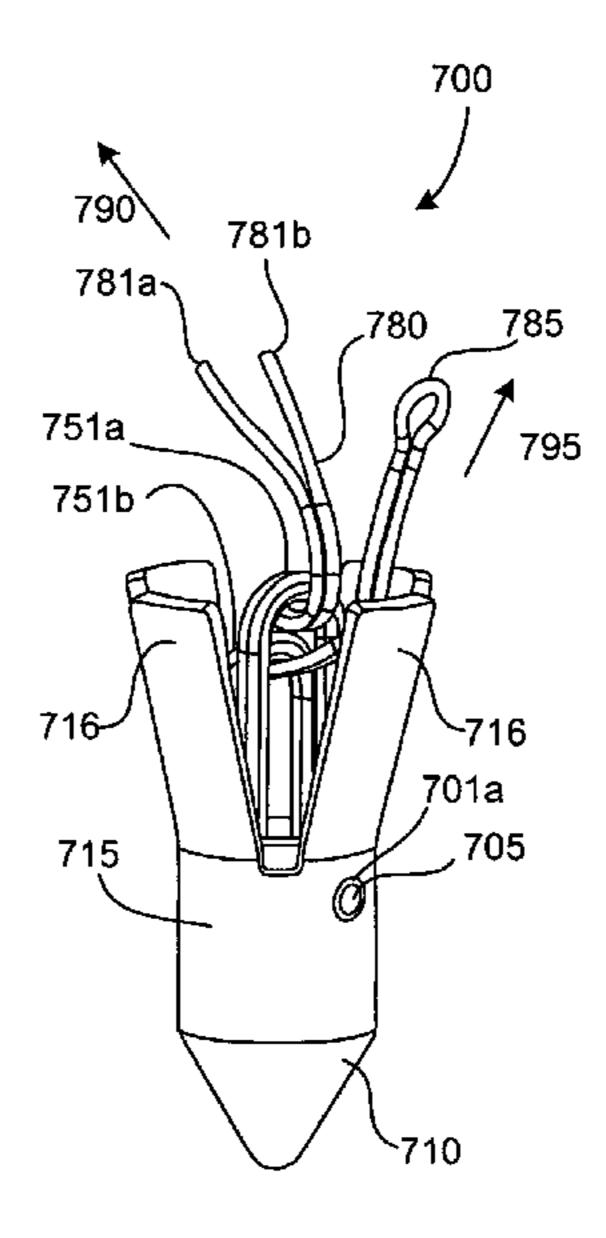
Primary Examiner — Julian W Woo Assistant Examiner — Jing Rui Ou

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(57) ABSTRACT

Systems, apparatuses and methods for securing tissue to bone using a bone anchoring system are described. Methods and apparatuses may allow transformation between locked and unlocked states, thereby allowing adjustment of the tension in the suture. The apparatus and/or methods may allow unidirectional movement of a suture, while preventing slippage or movement of the suture and tissue in the opposite direction. Ends of a suture may be individually tensioned to adjust positioning of a tissue with respect to a bone.

27 Claims, 23 Drawing Sheets



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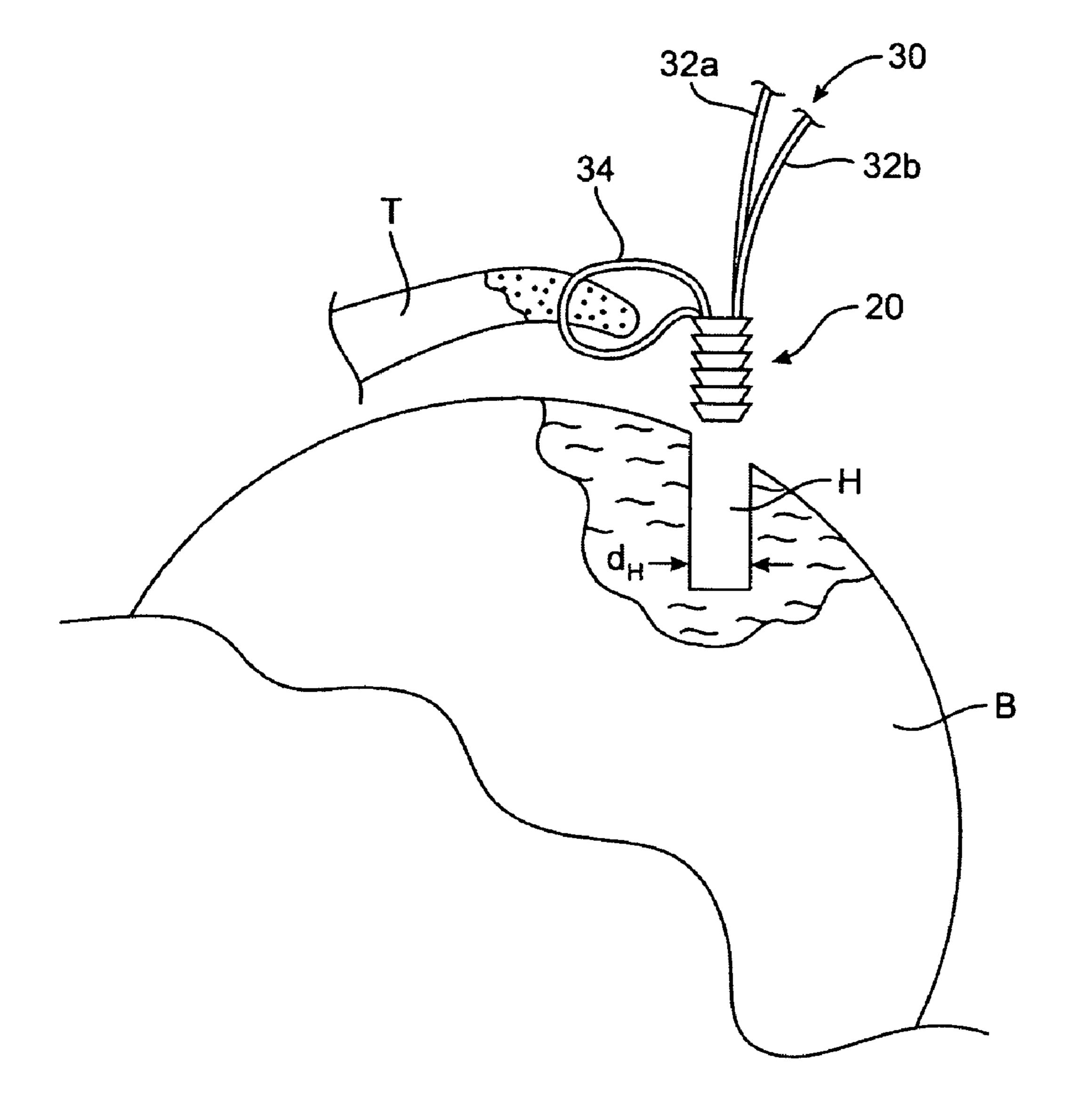
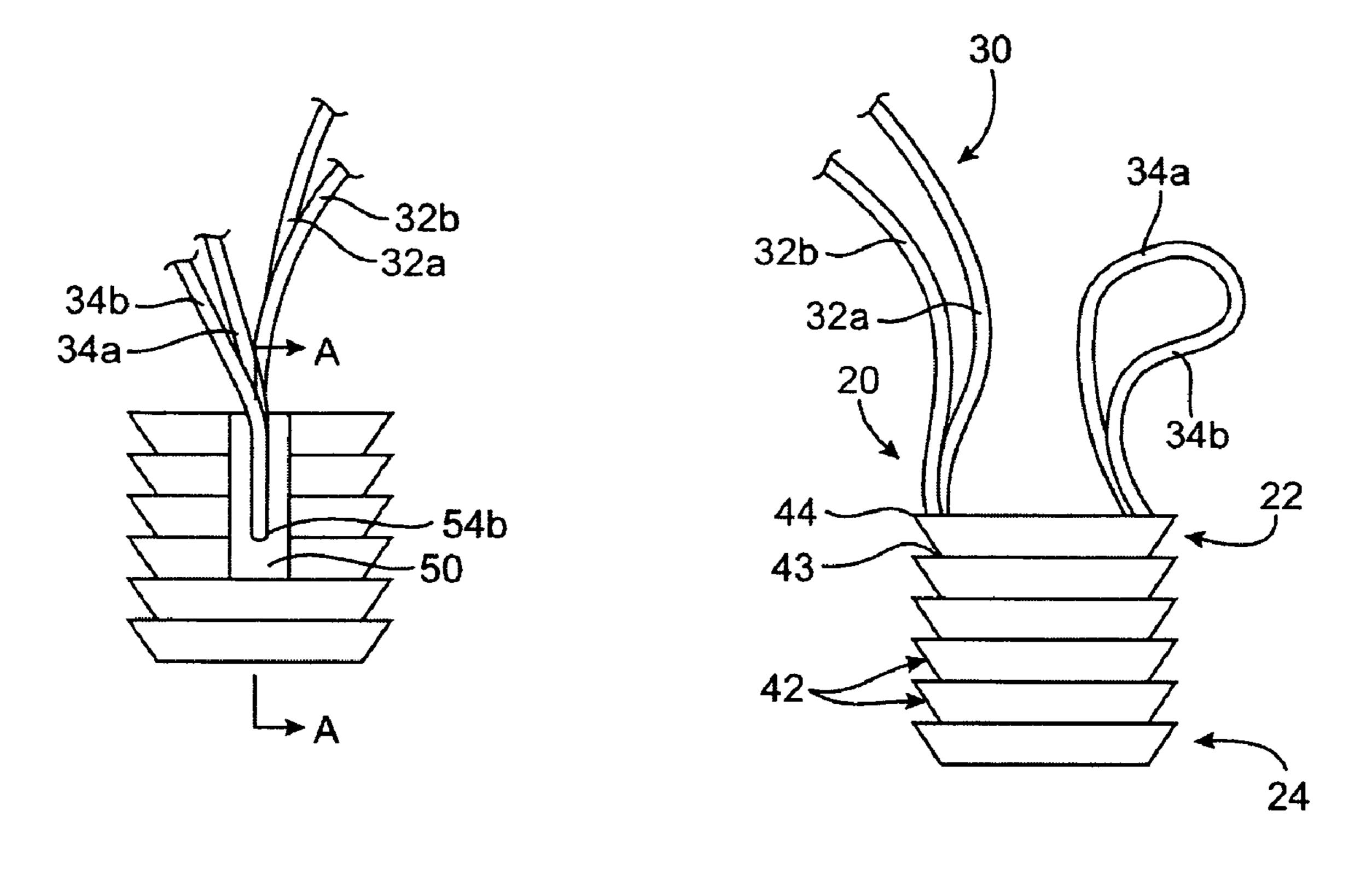


FIG. 1





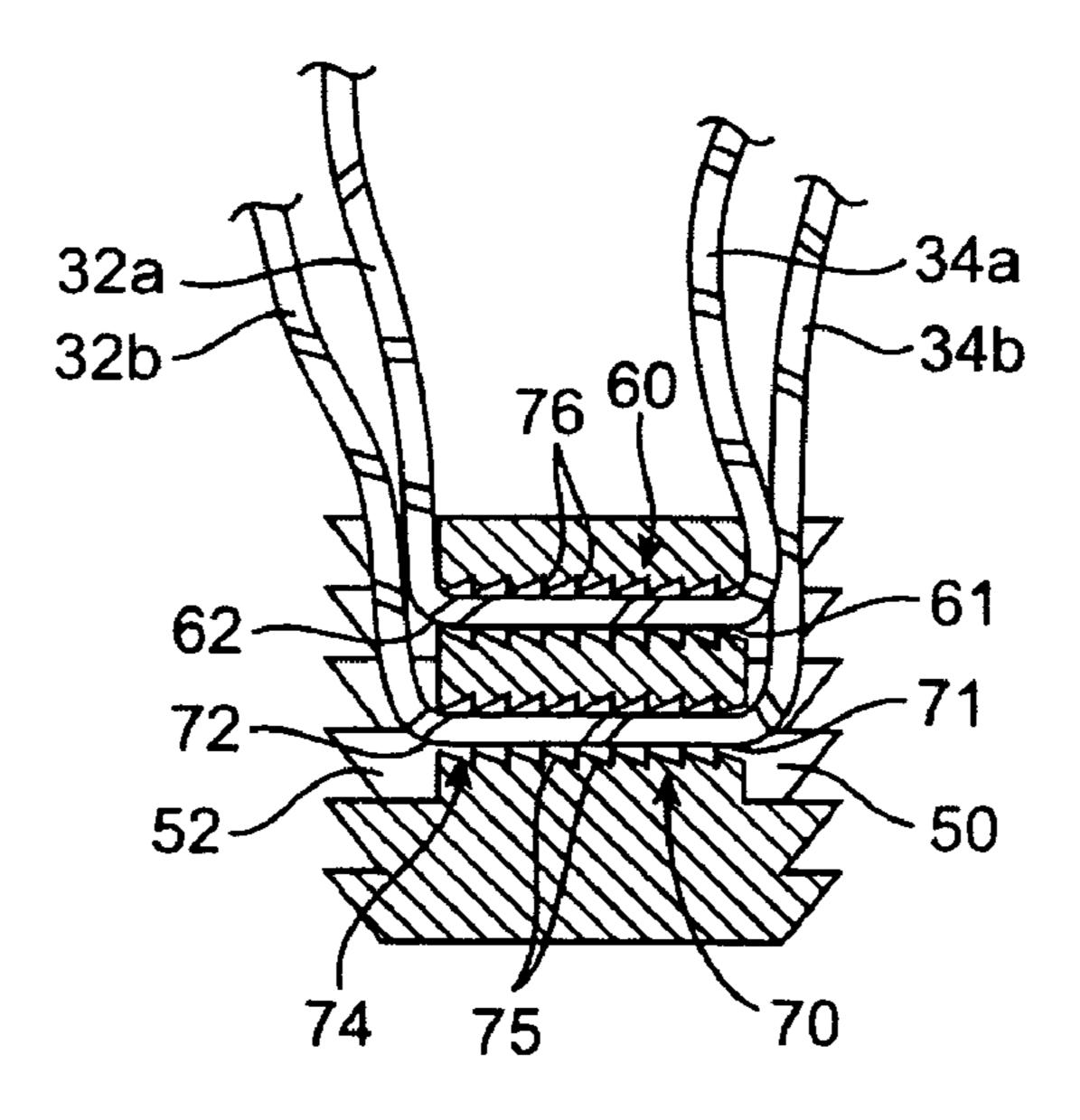
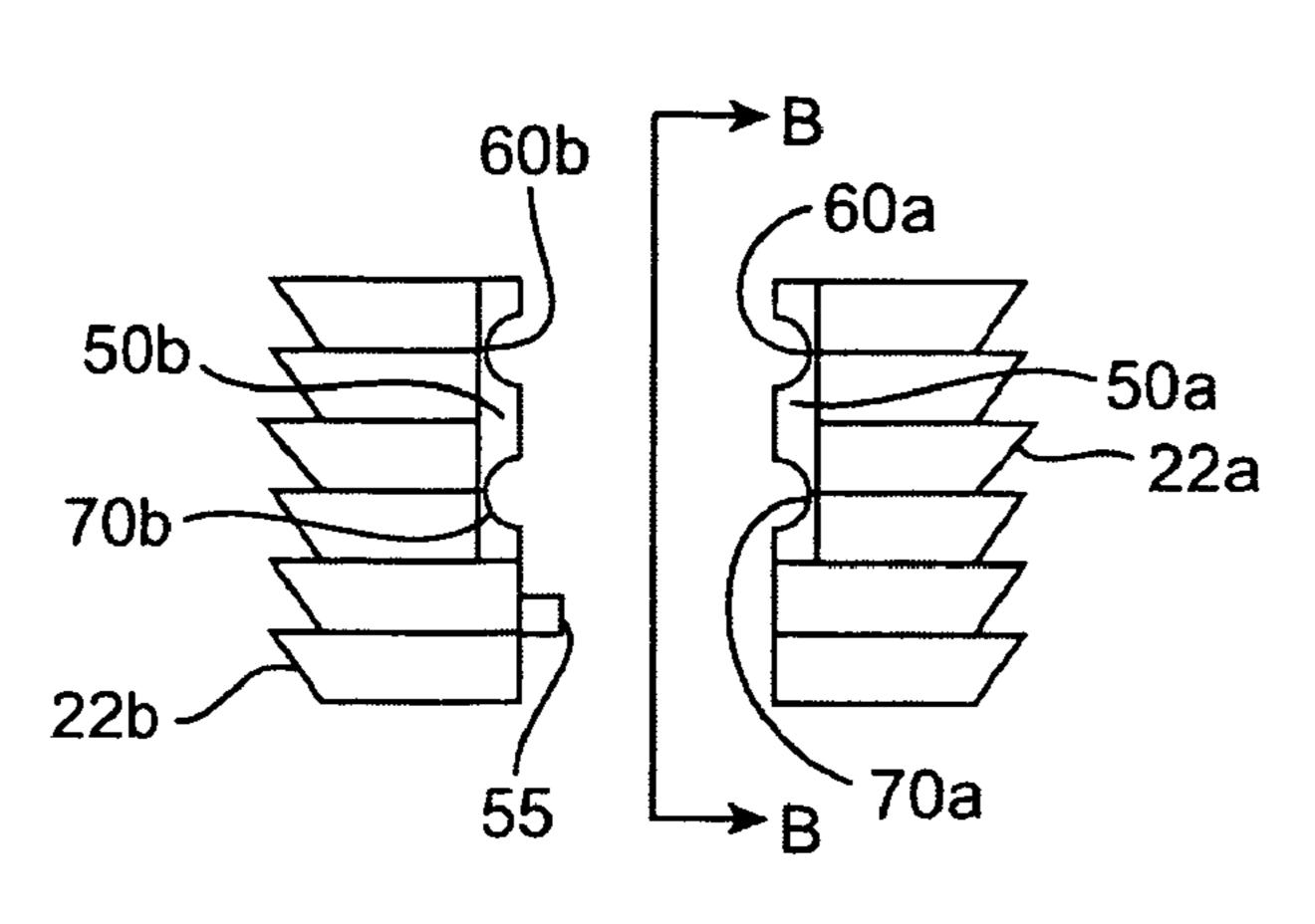


FIG. 2C



60' 22b -70'

FIG. 3A

FIG. 3B

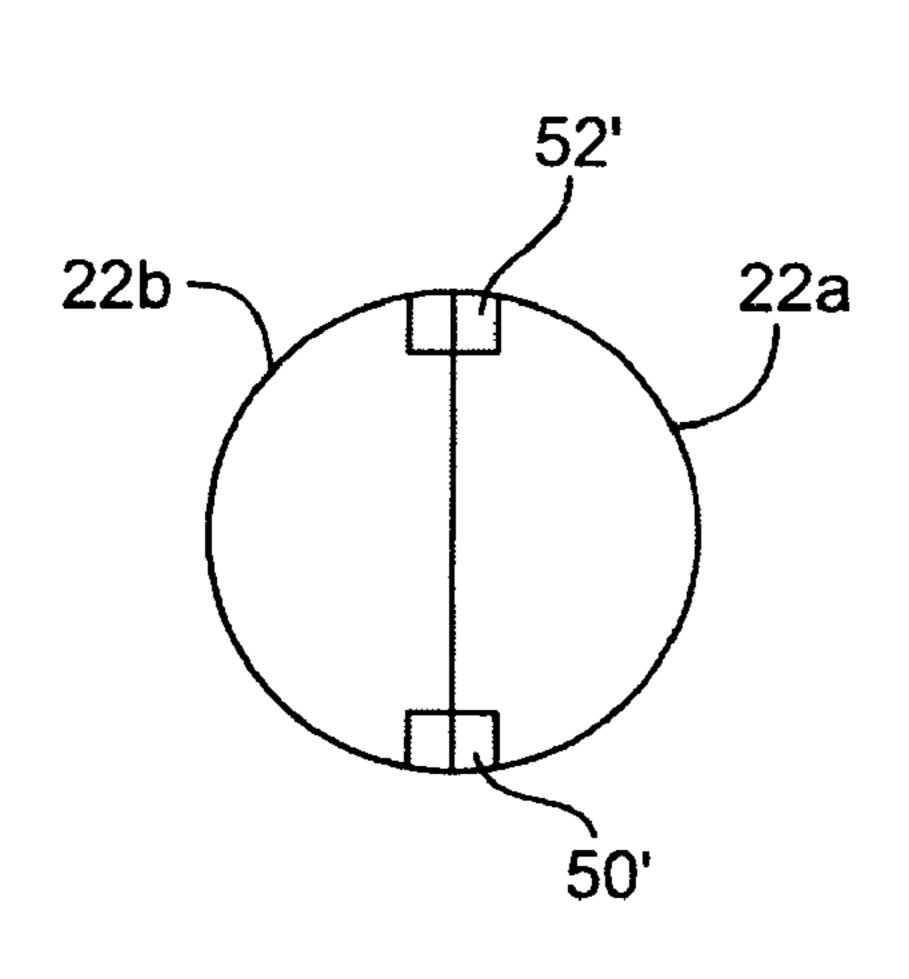


FIG. 3C

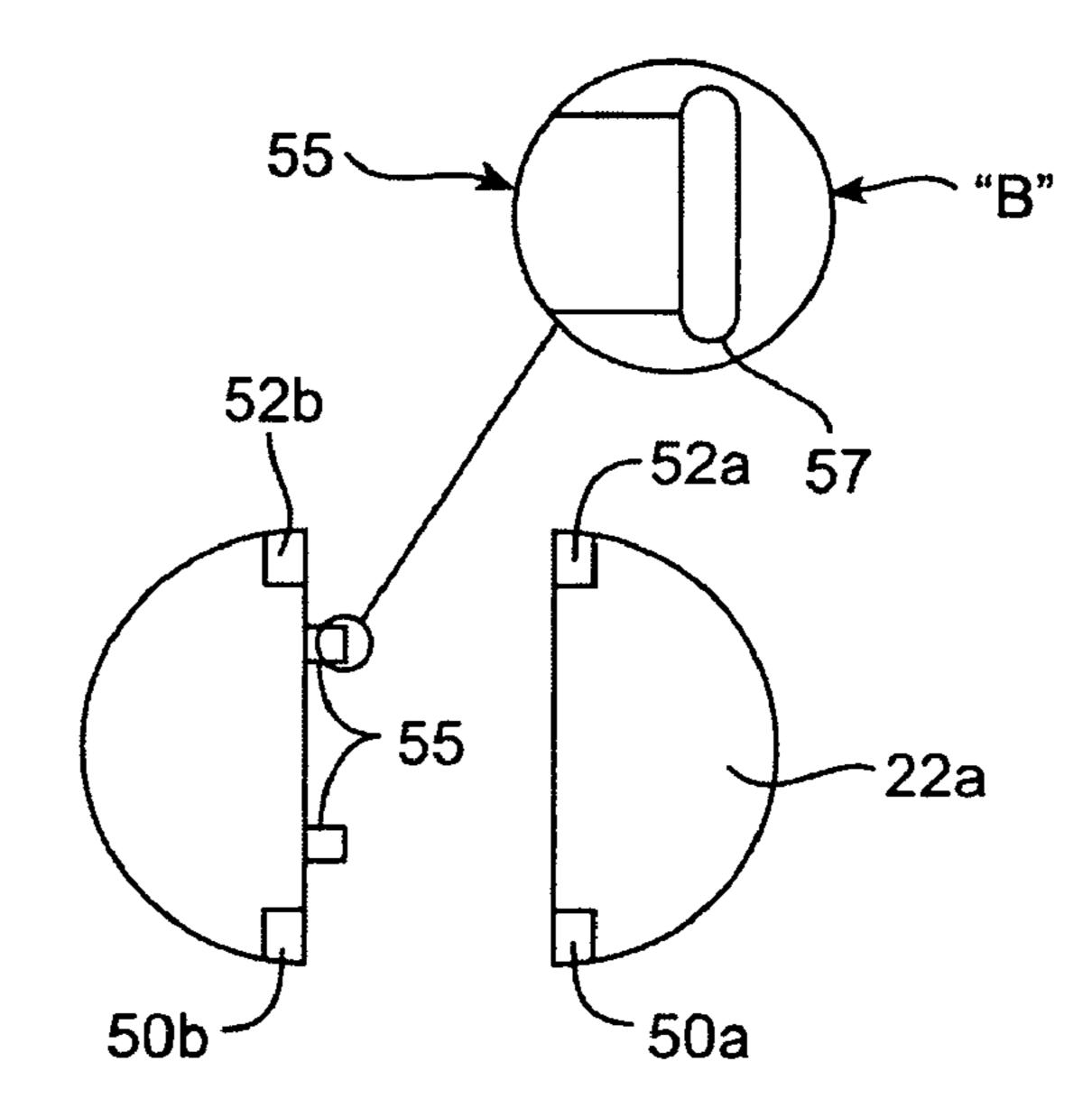


FIG. 3D

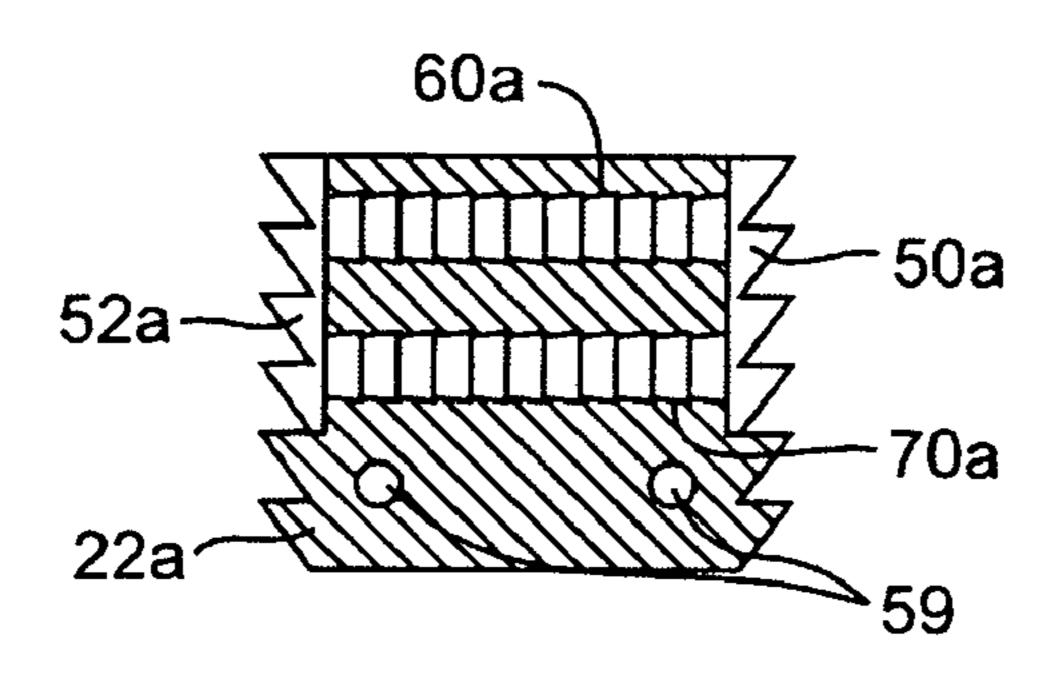
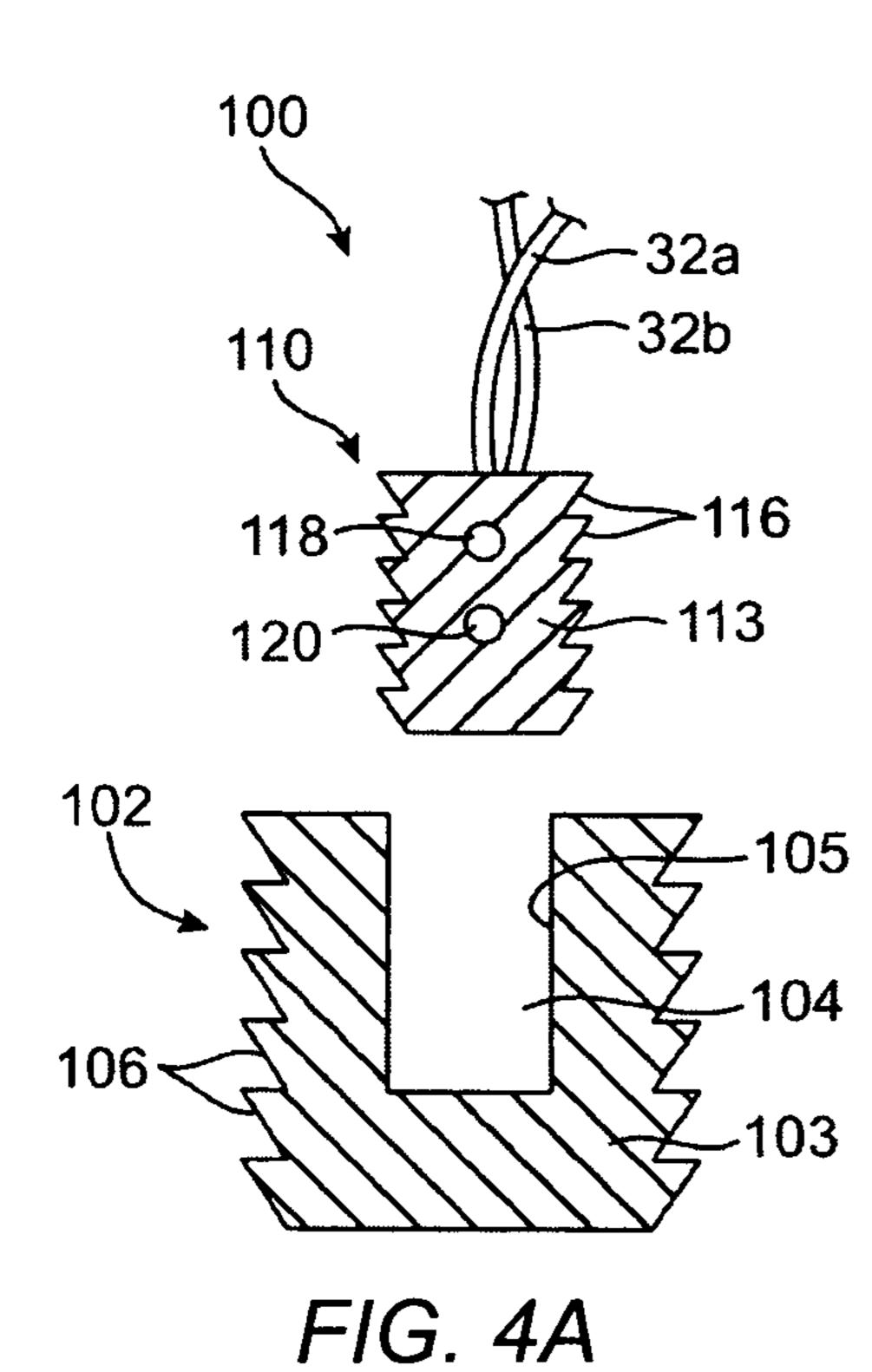
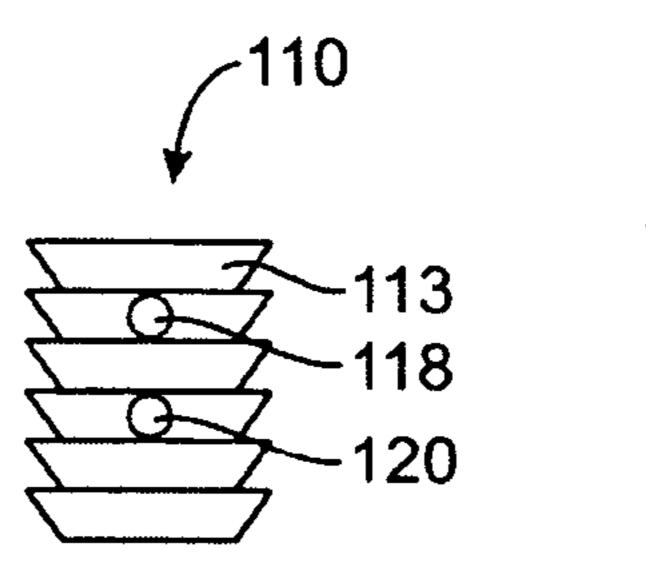


FIG. 3E





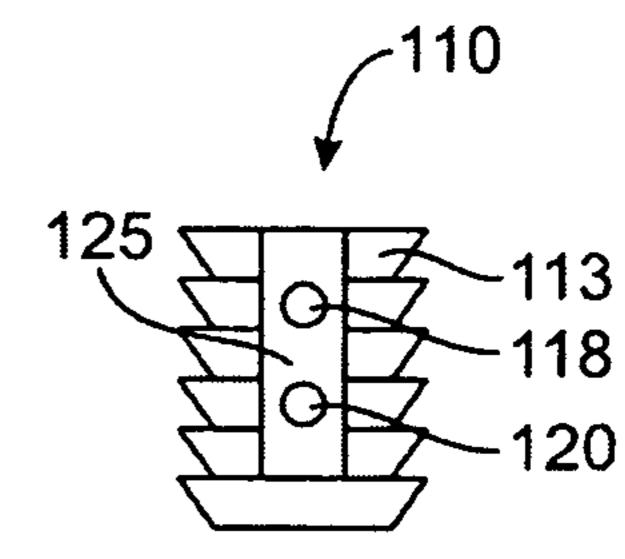
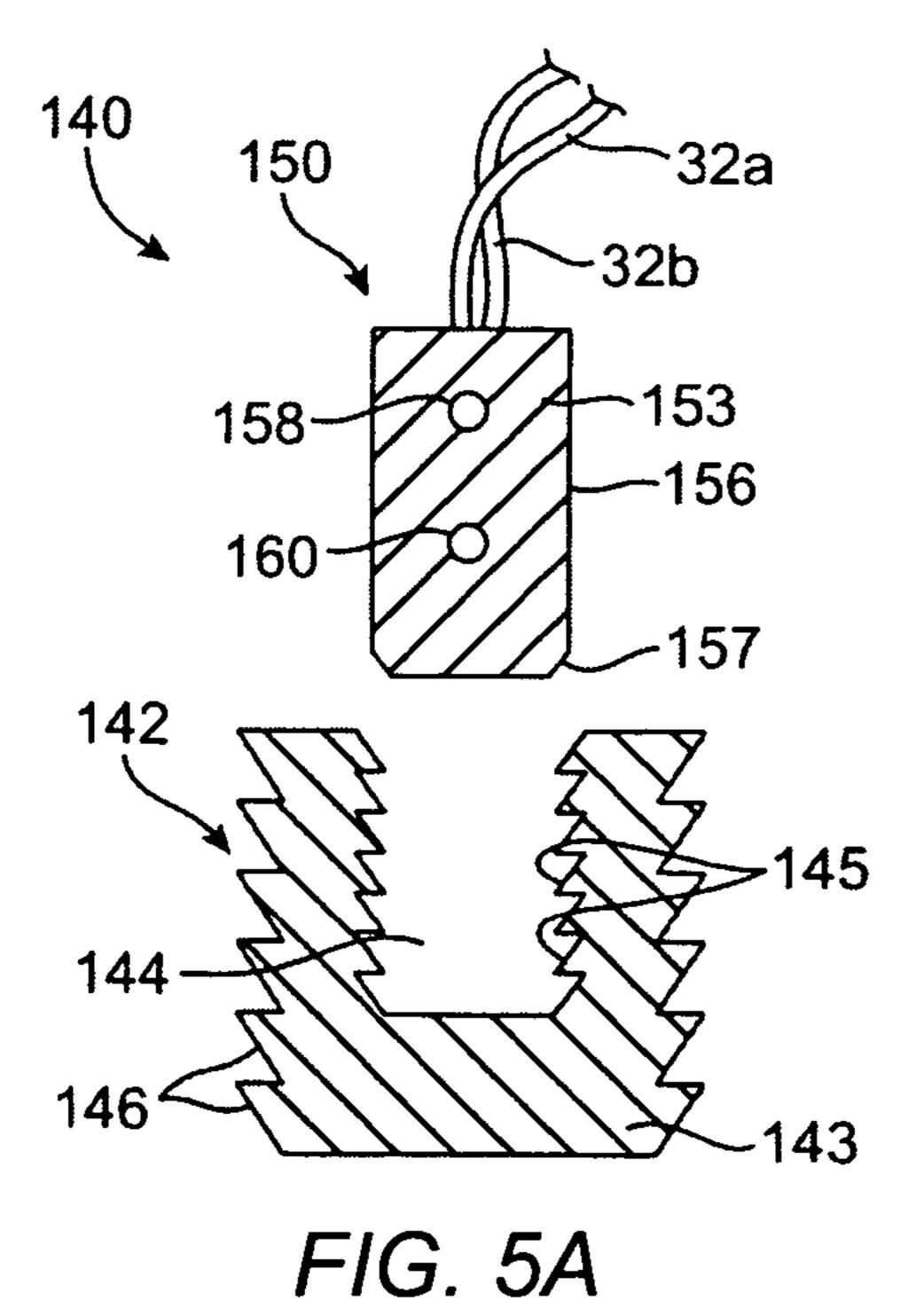
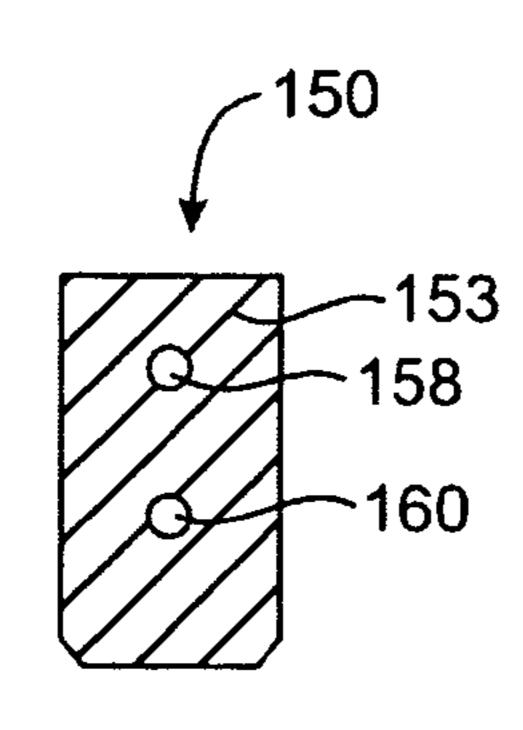


FIG. 4B

FIG. 4C





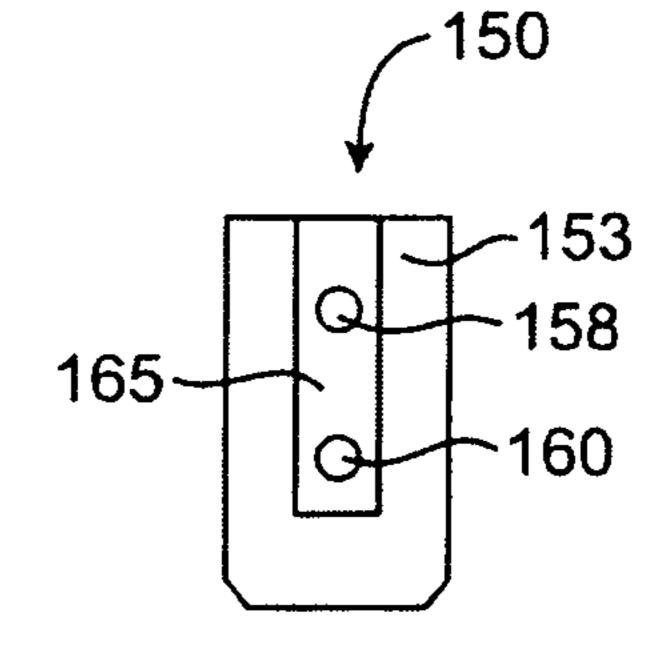
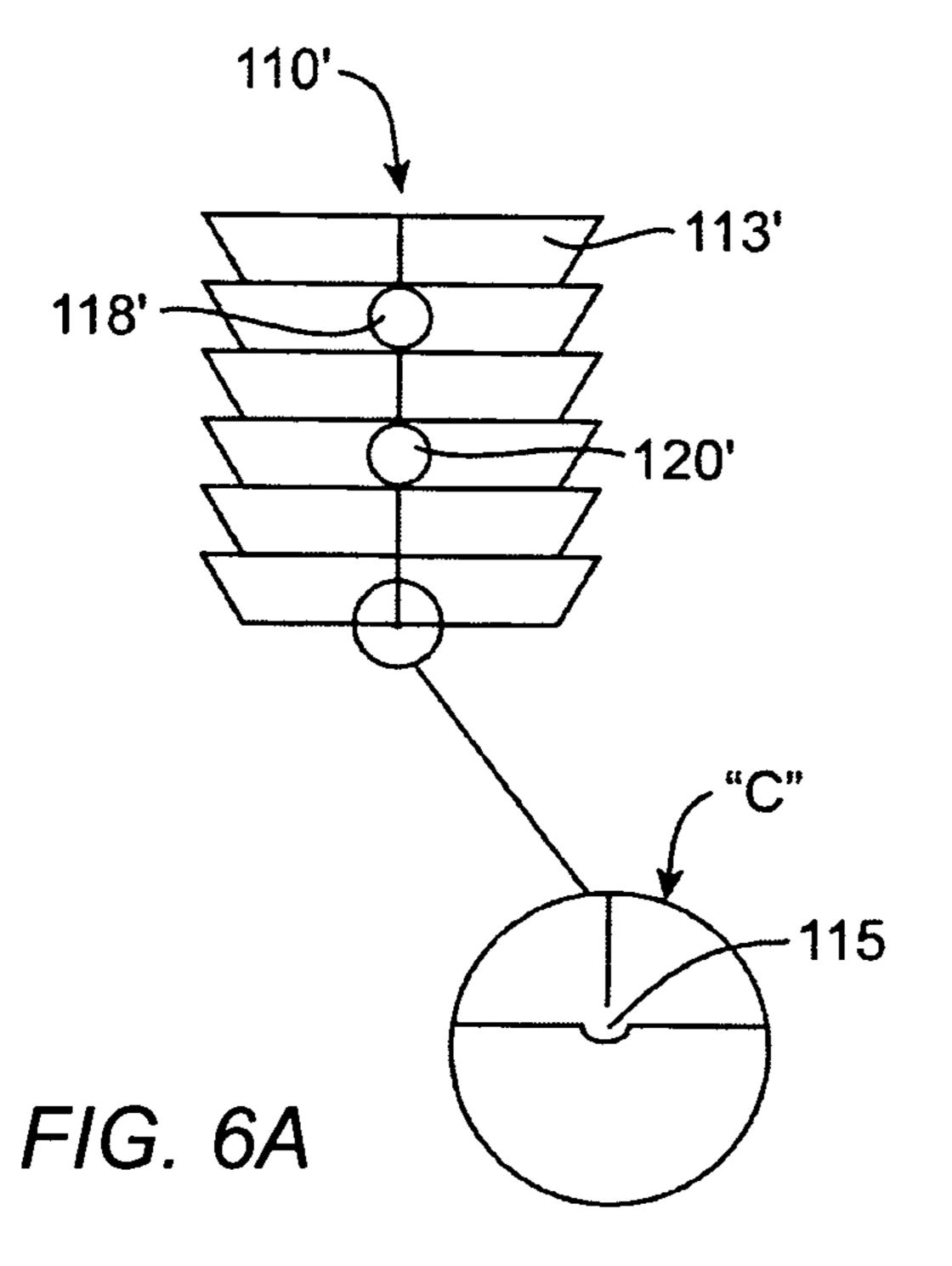


FIG. 5B

F/G. 5C



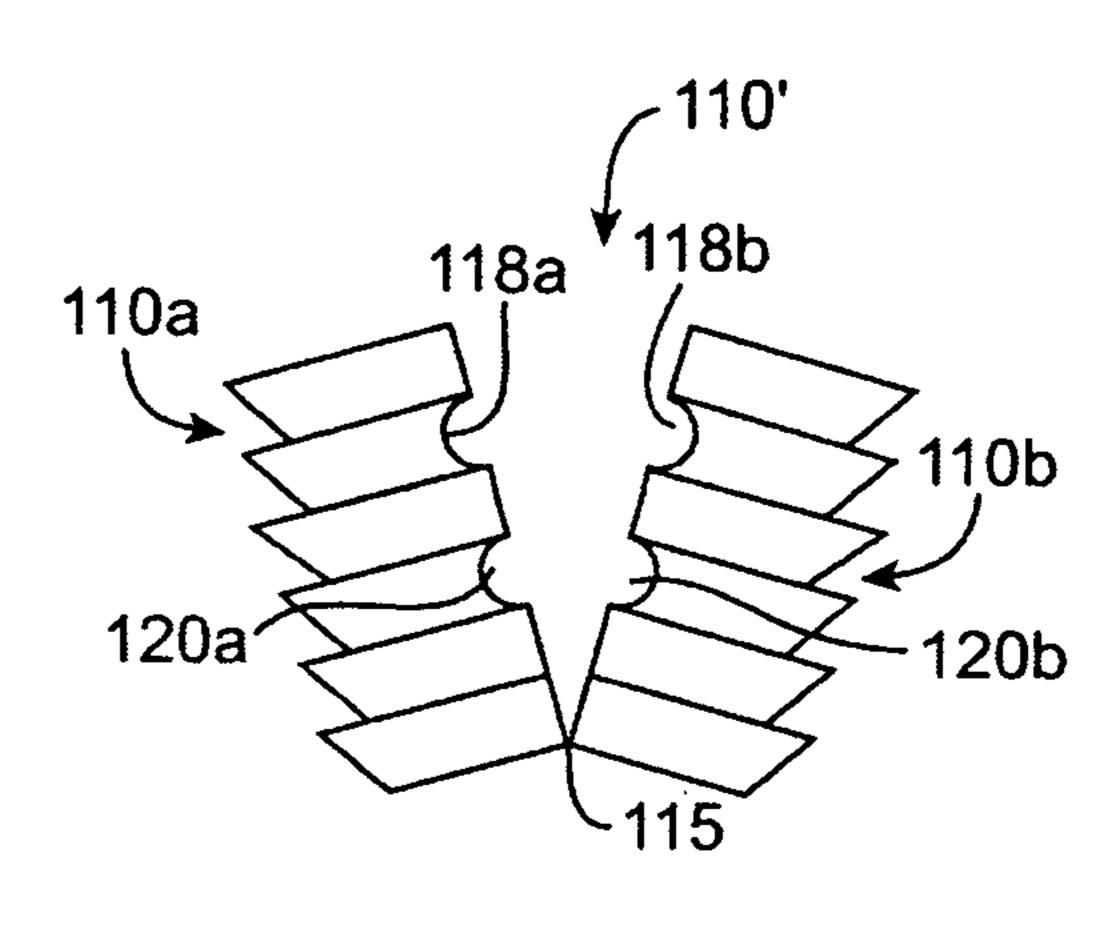


FIG. 6B

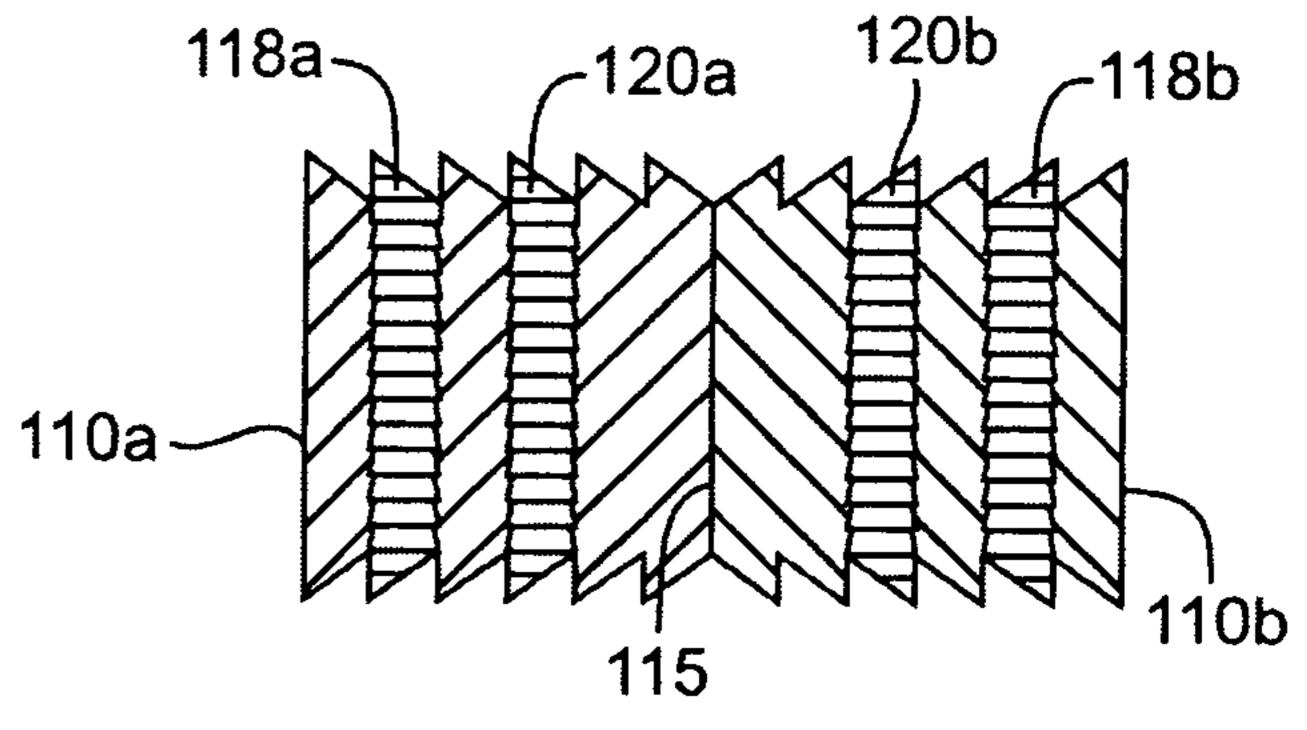


FIG. 6C

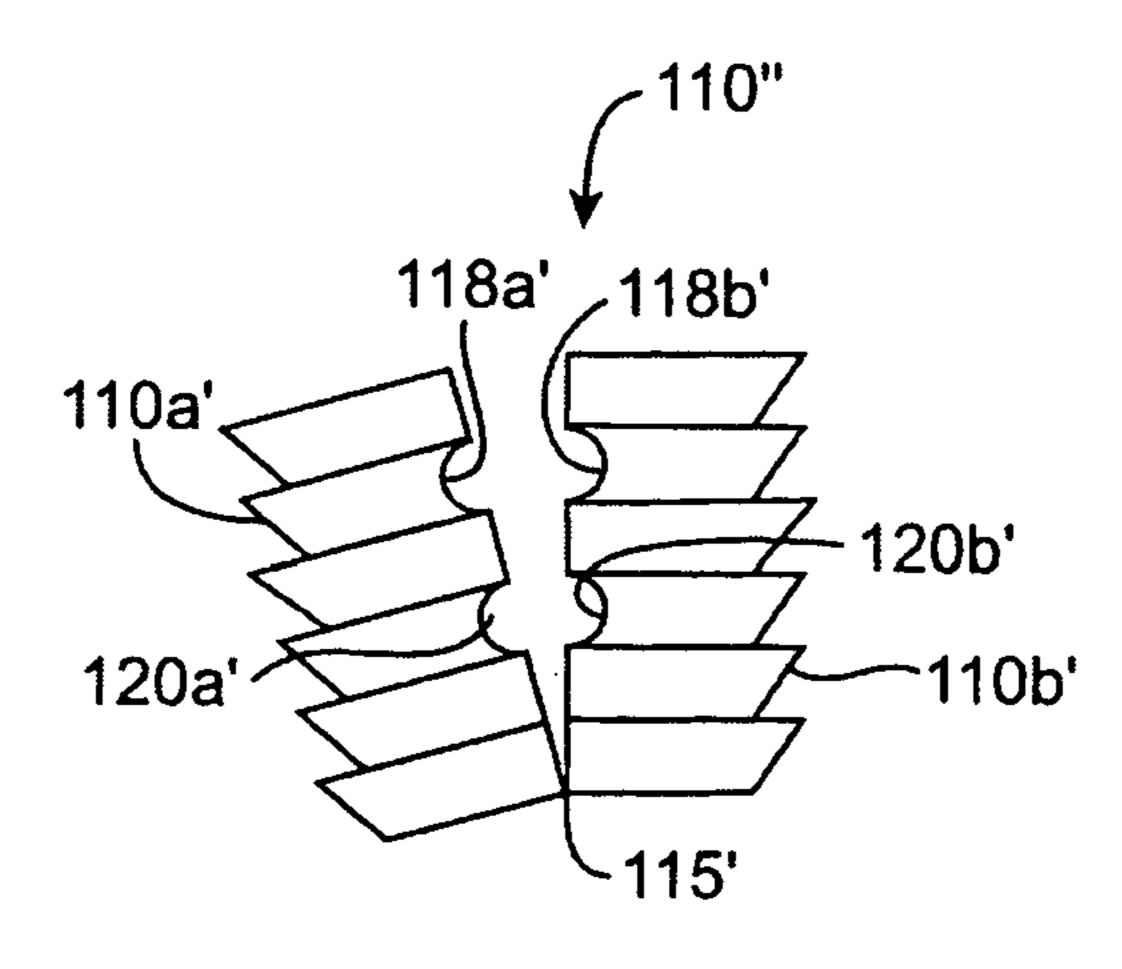
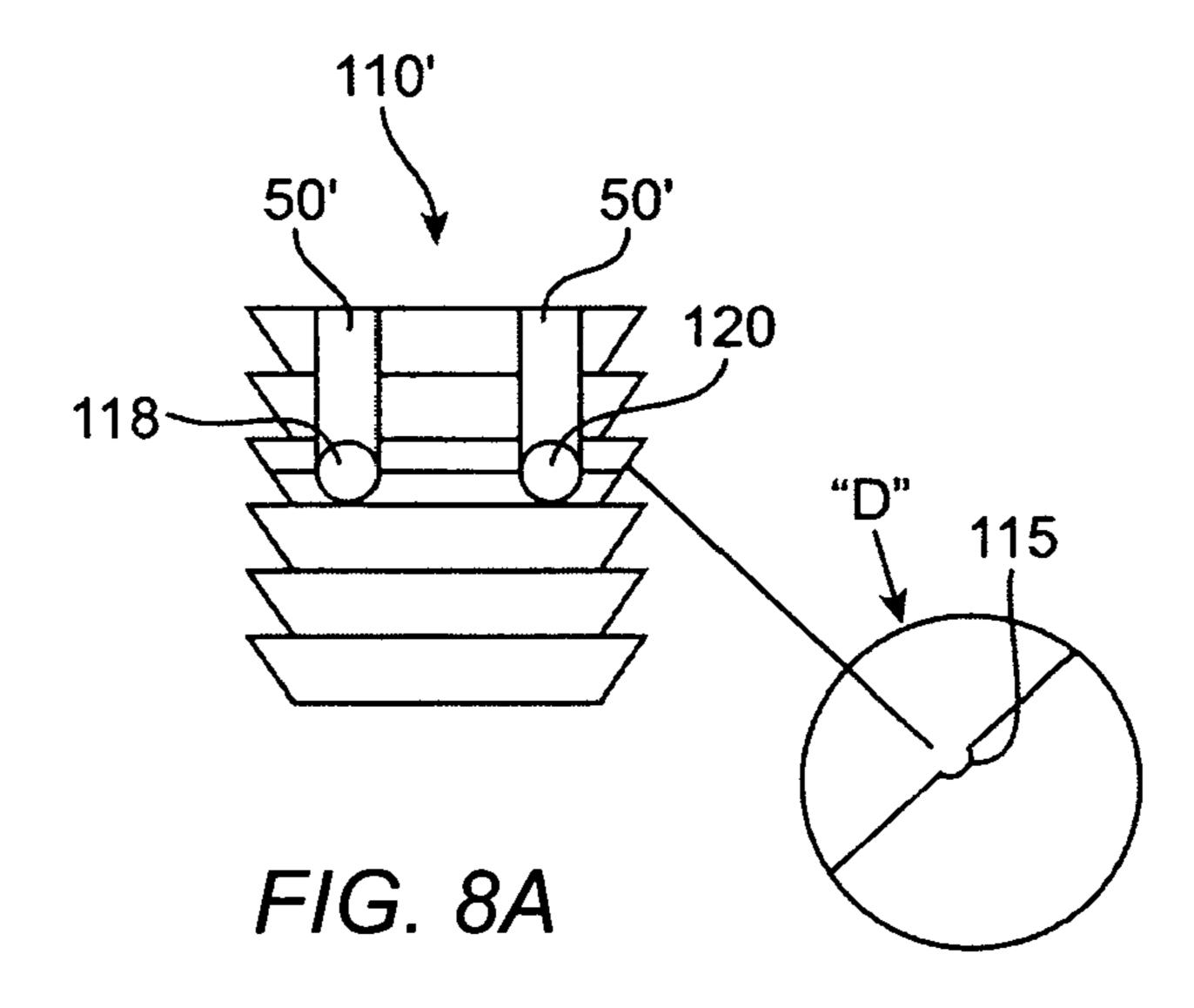
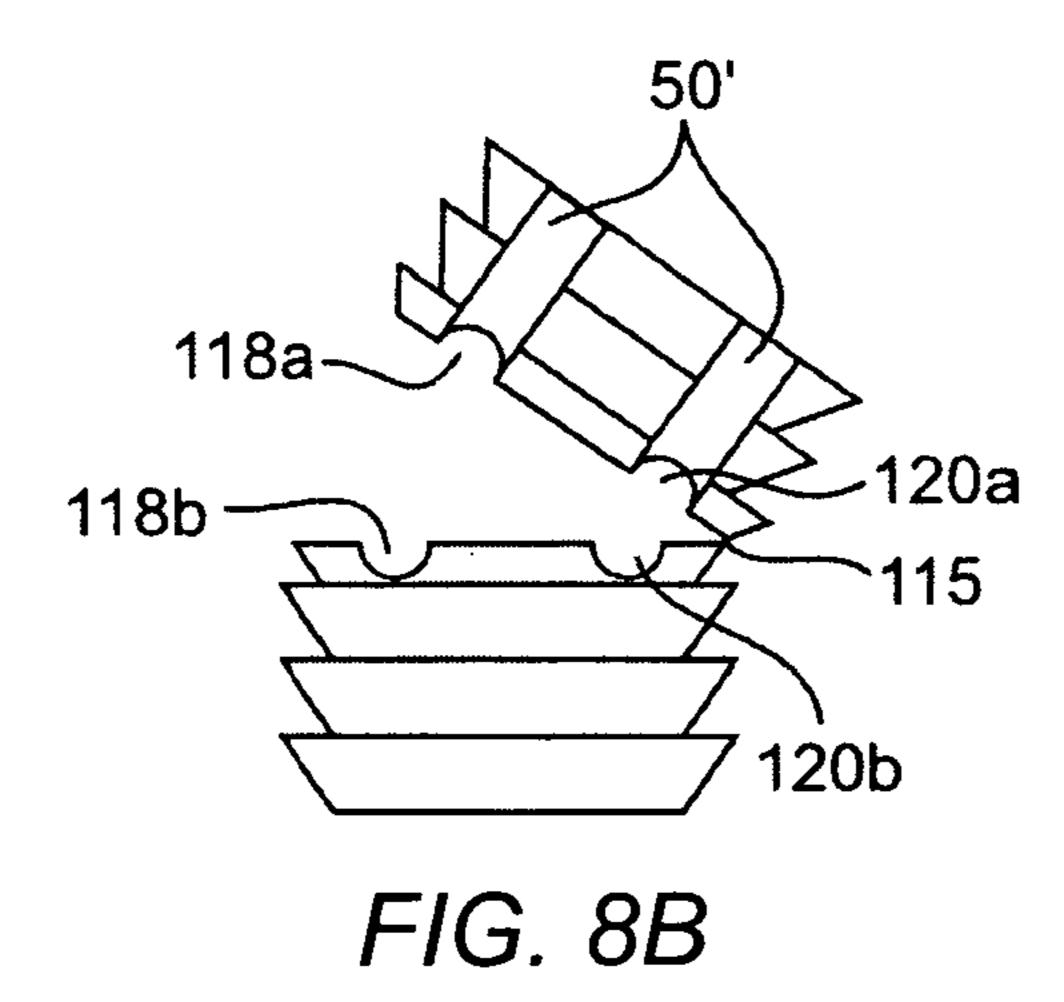


FIG. 7





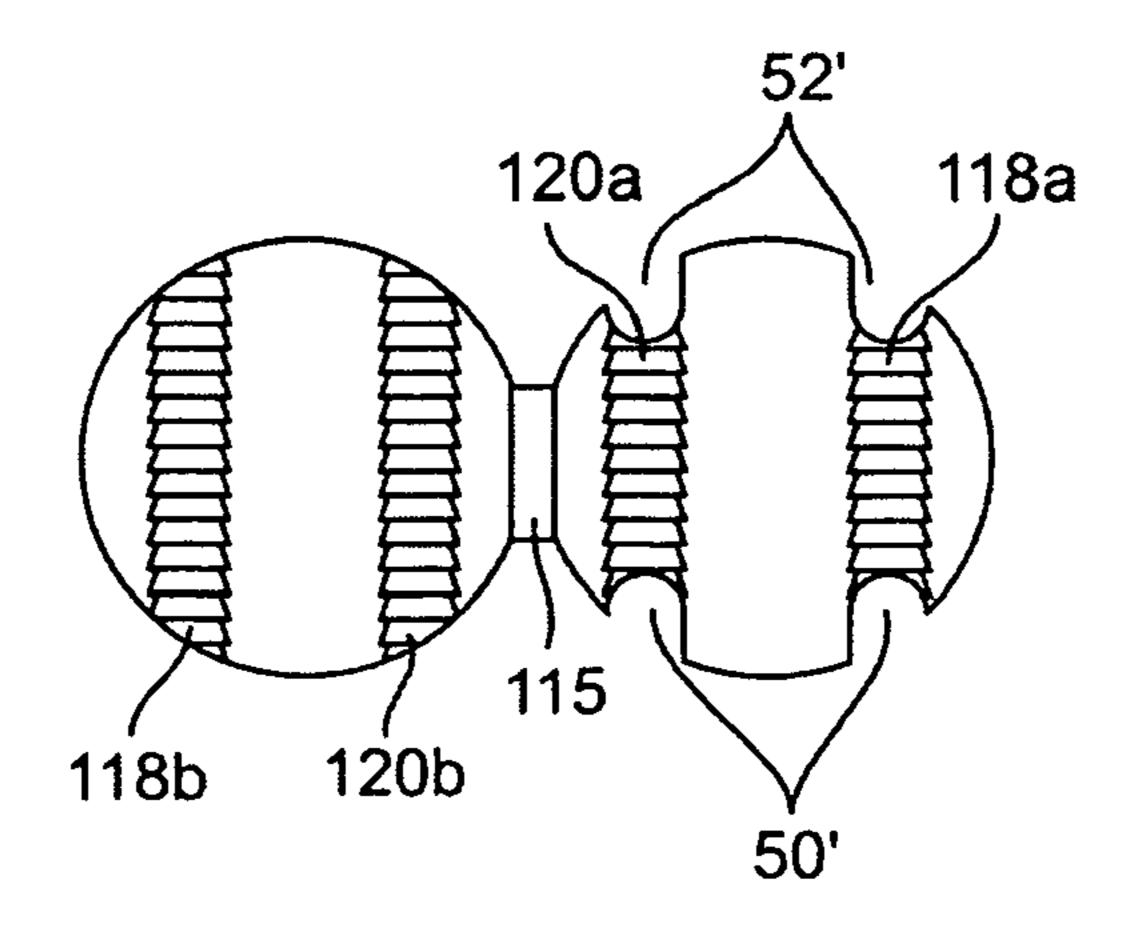
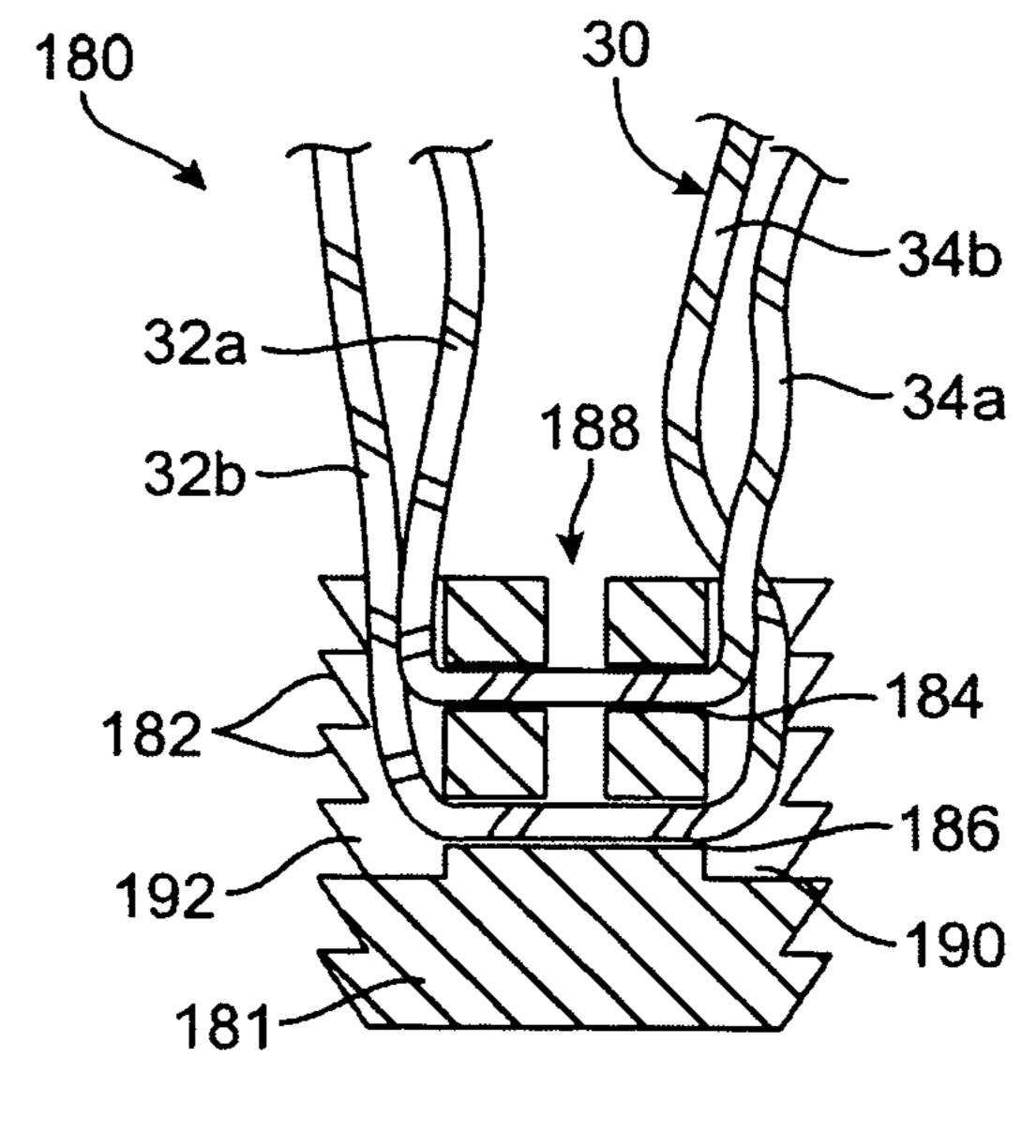
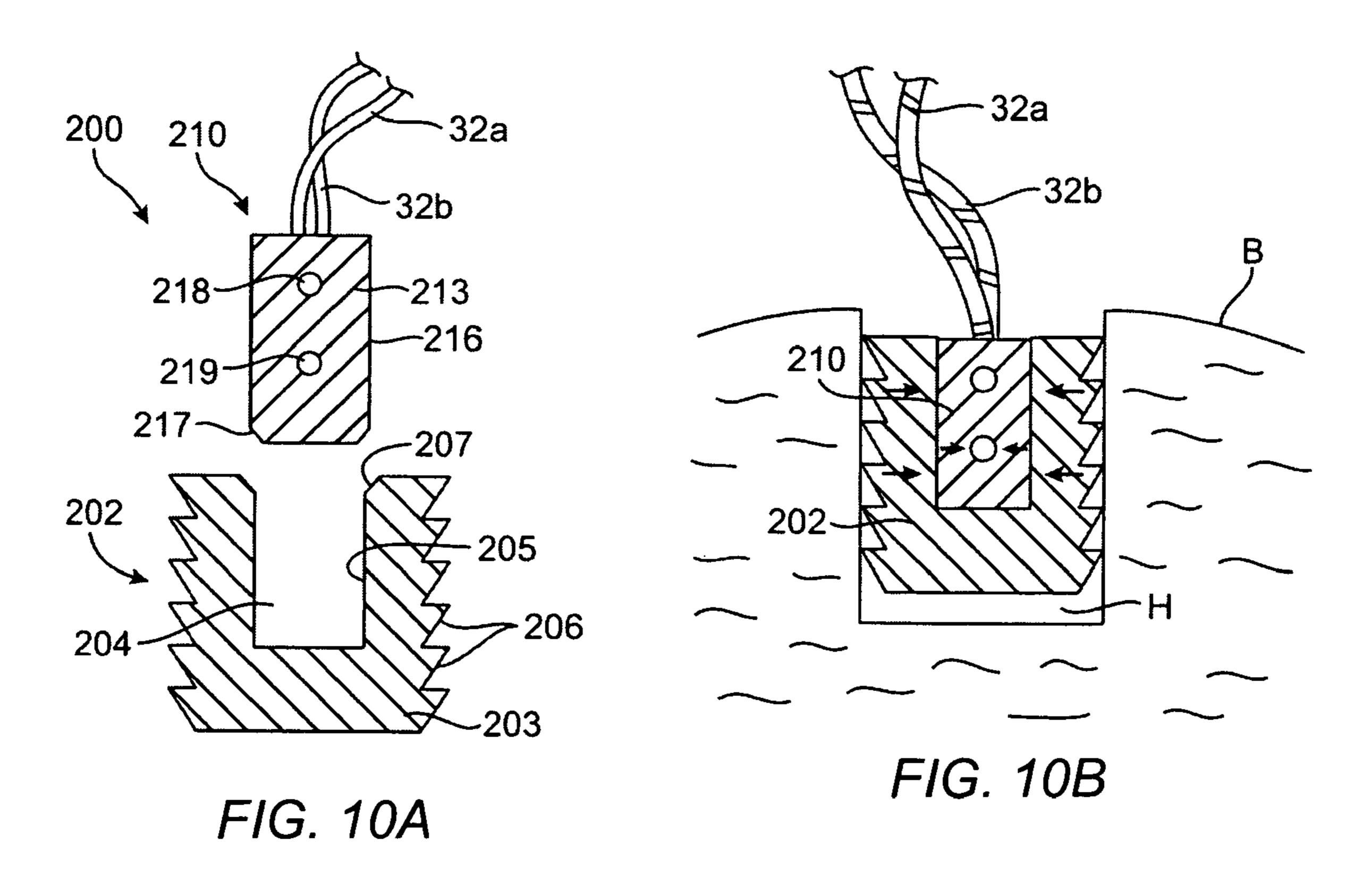
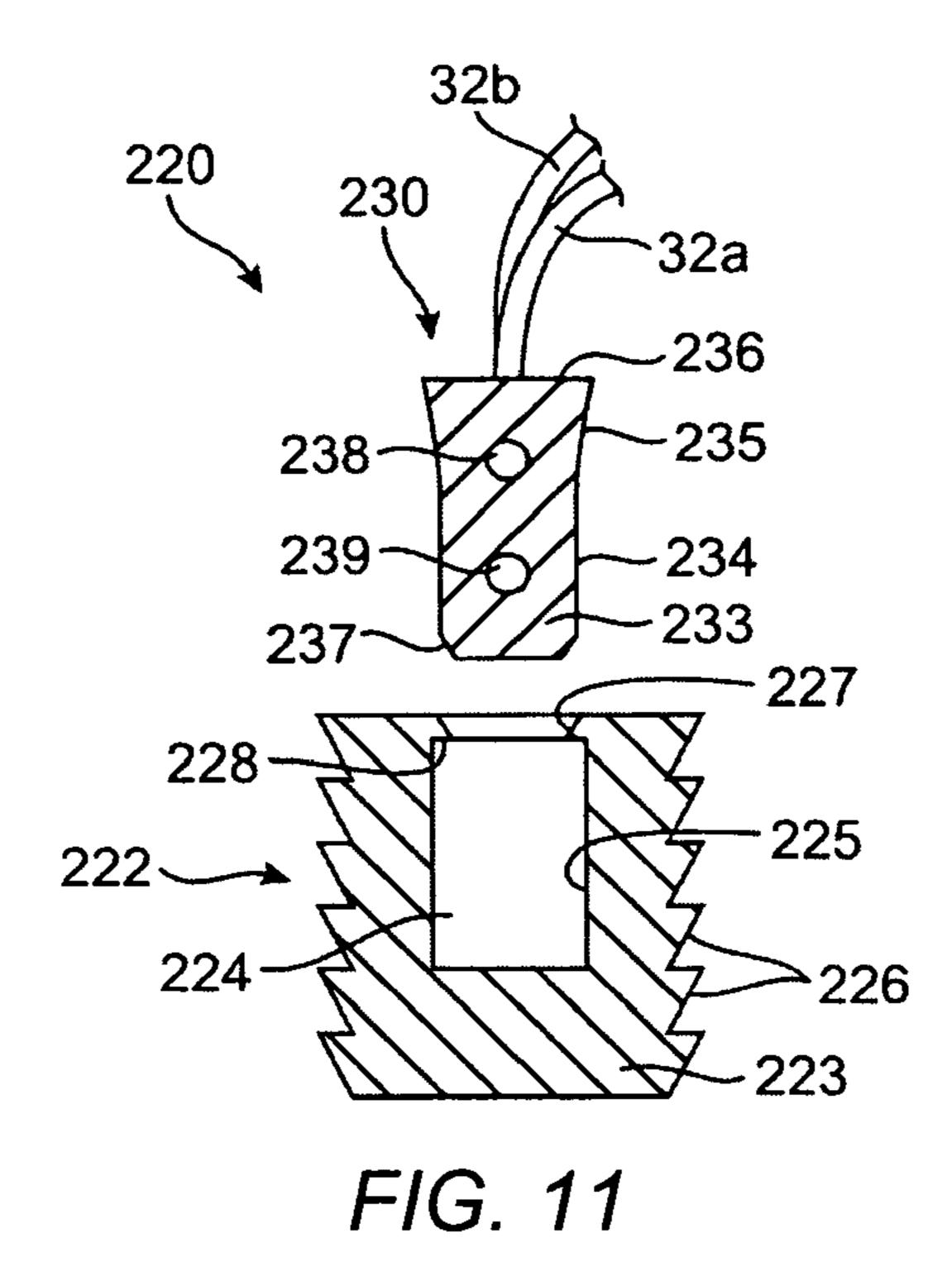


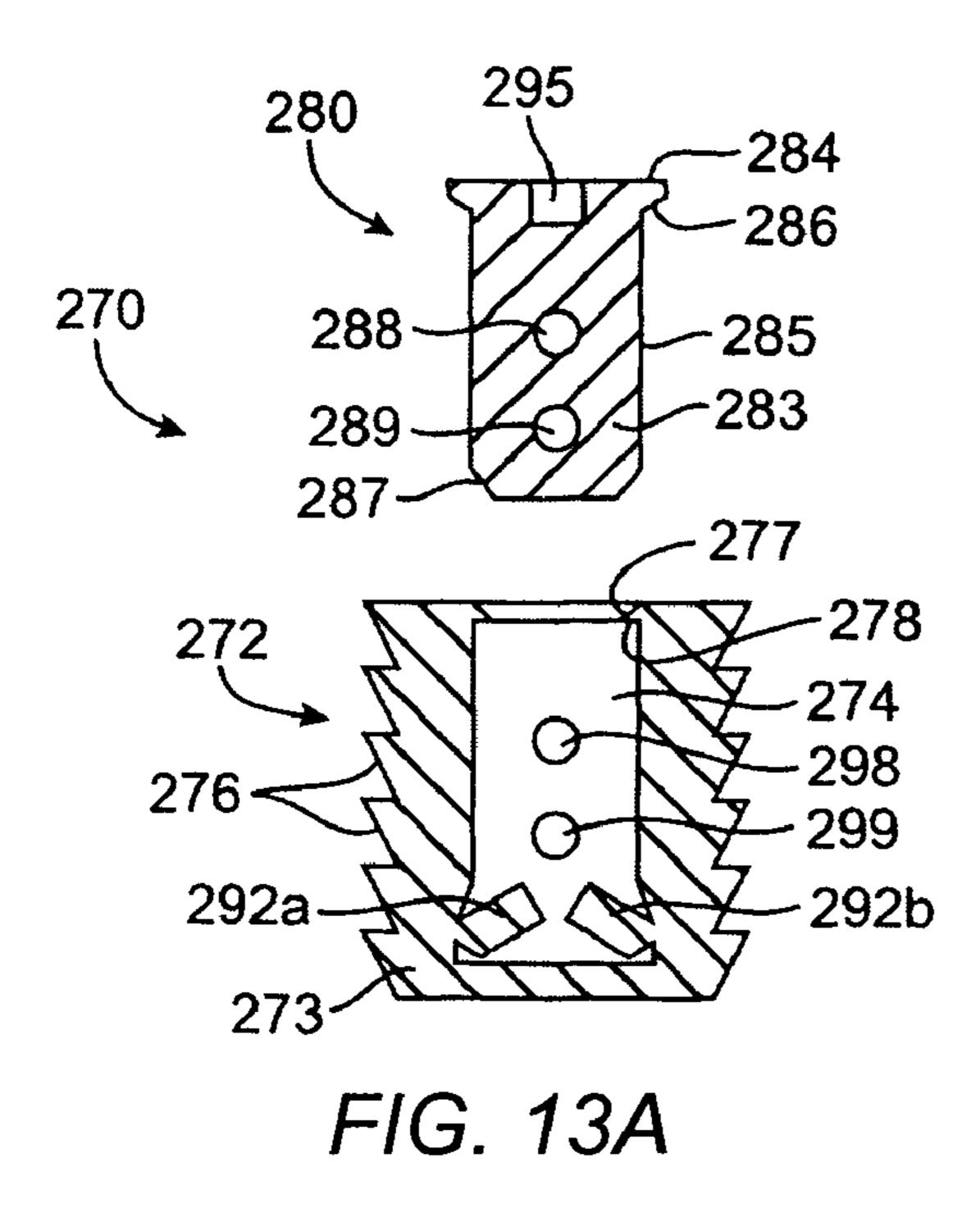
FIG. 8C



F/G. 9







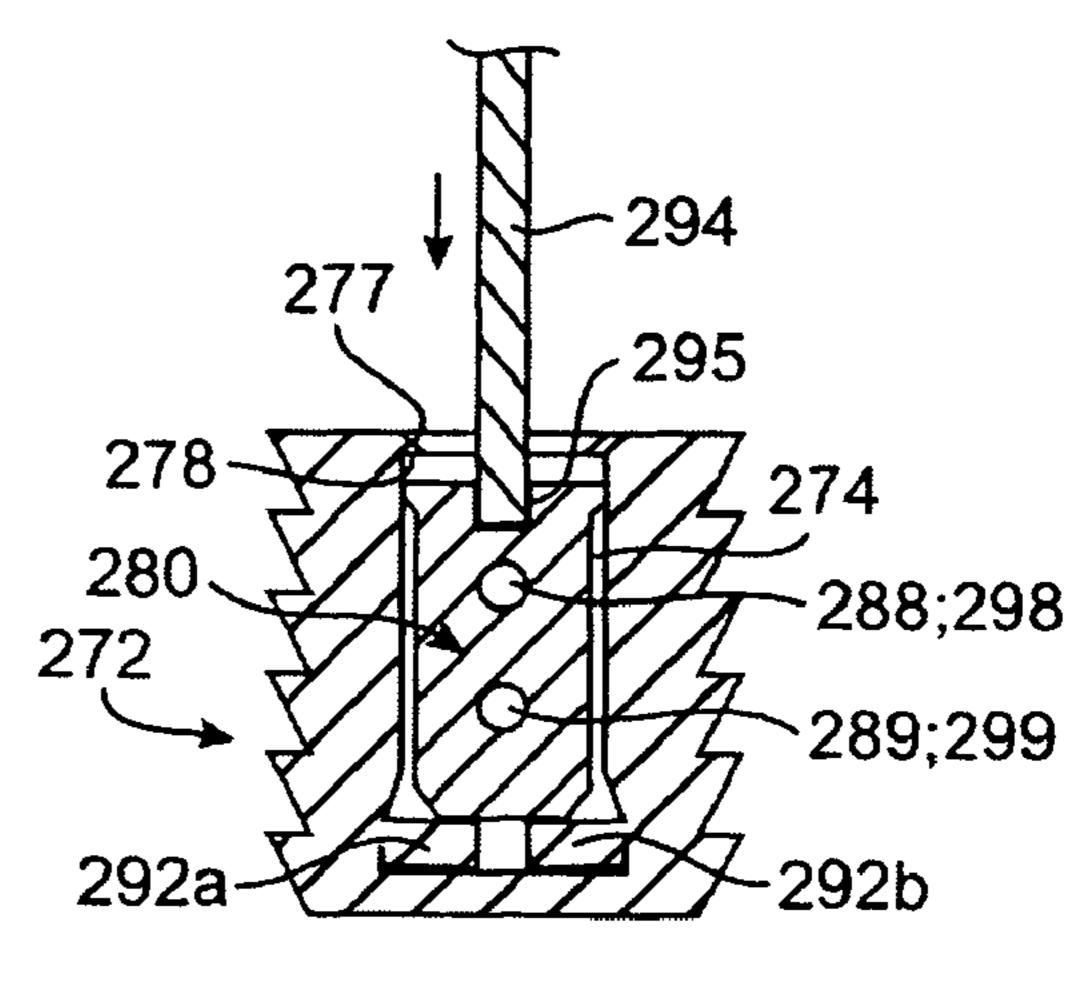
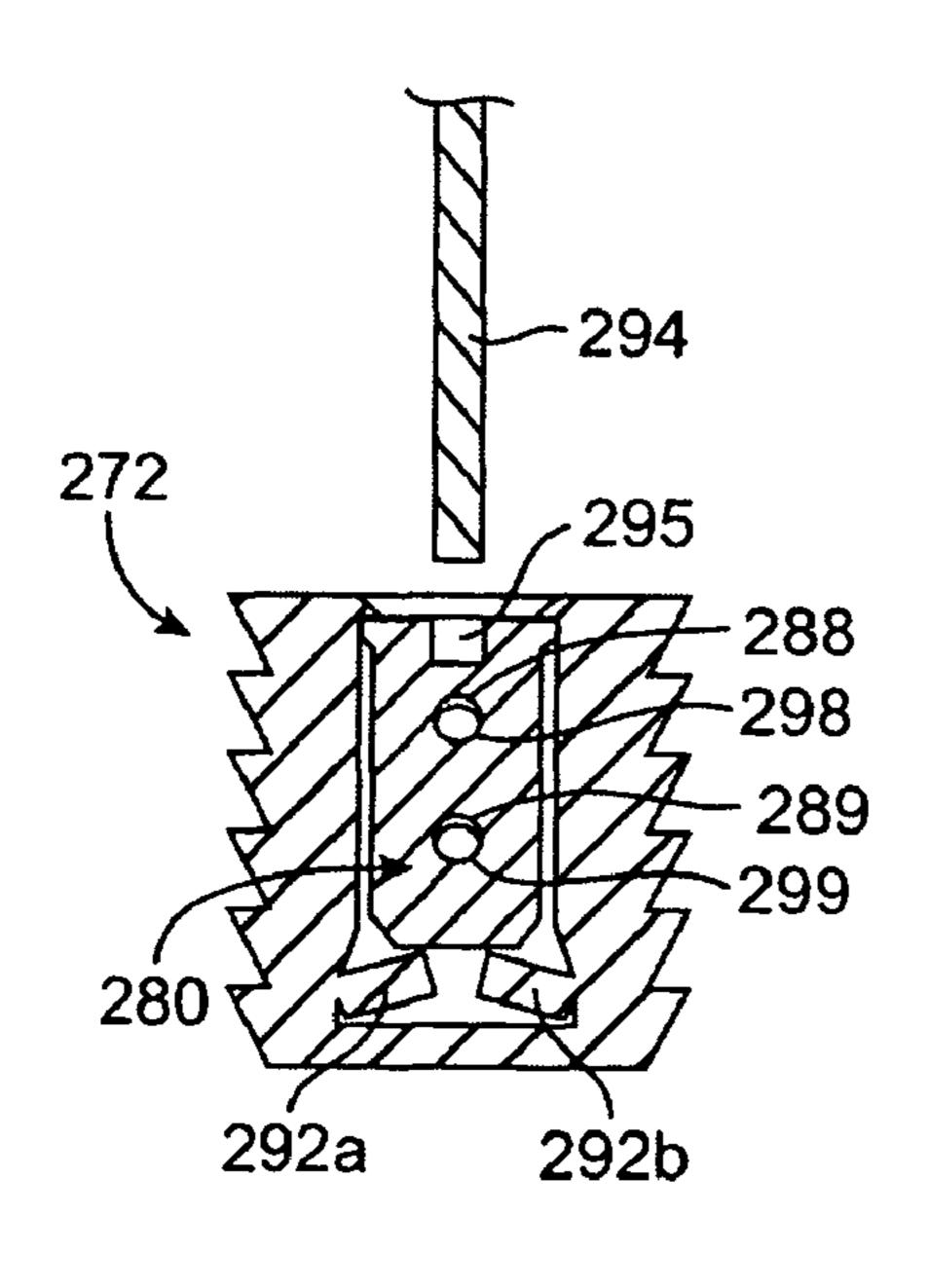
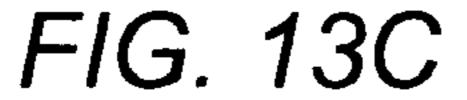


FIG. 13B





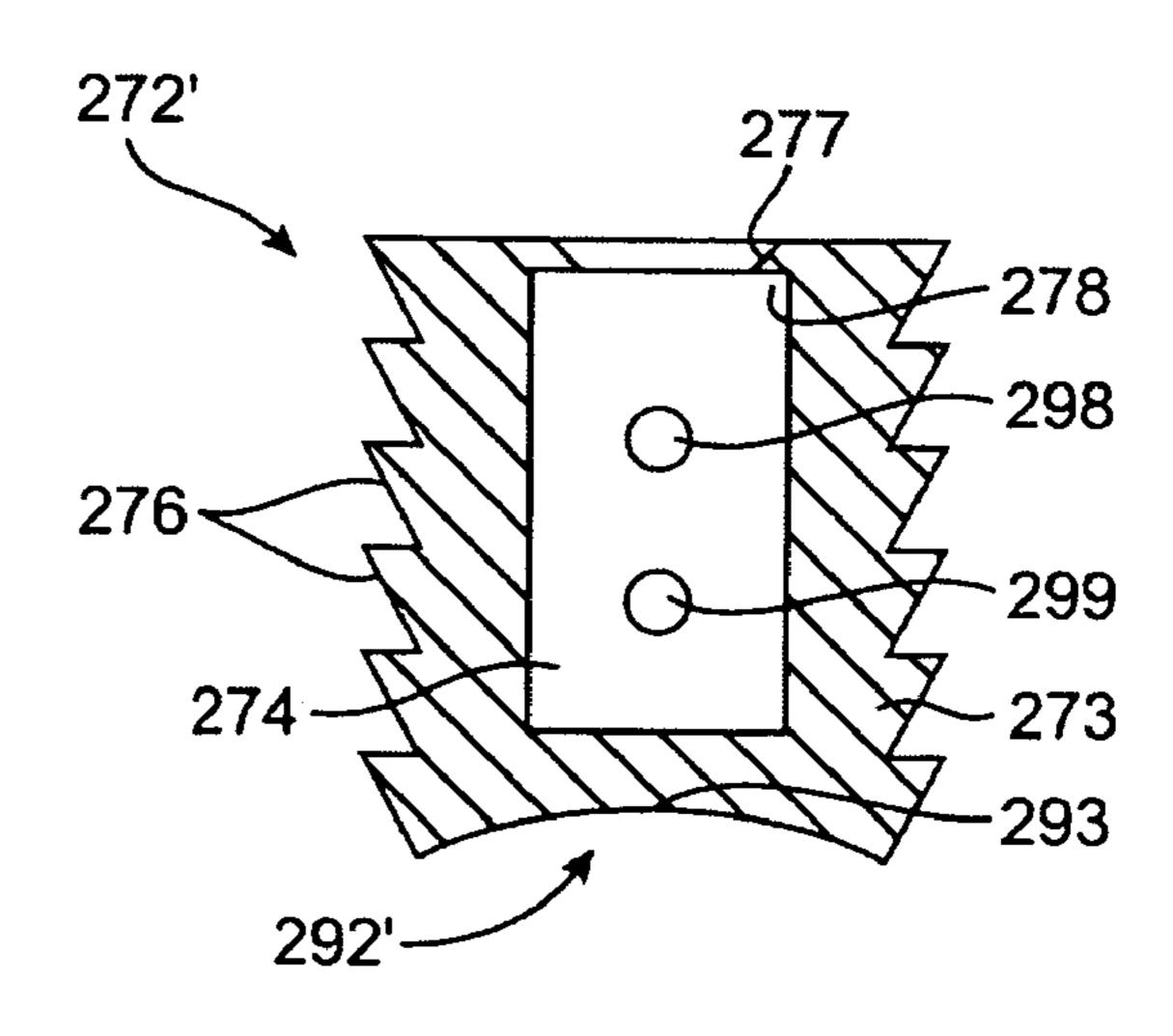


FIG. 14

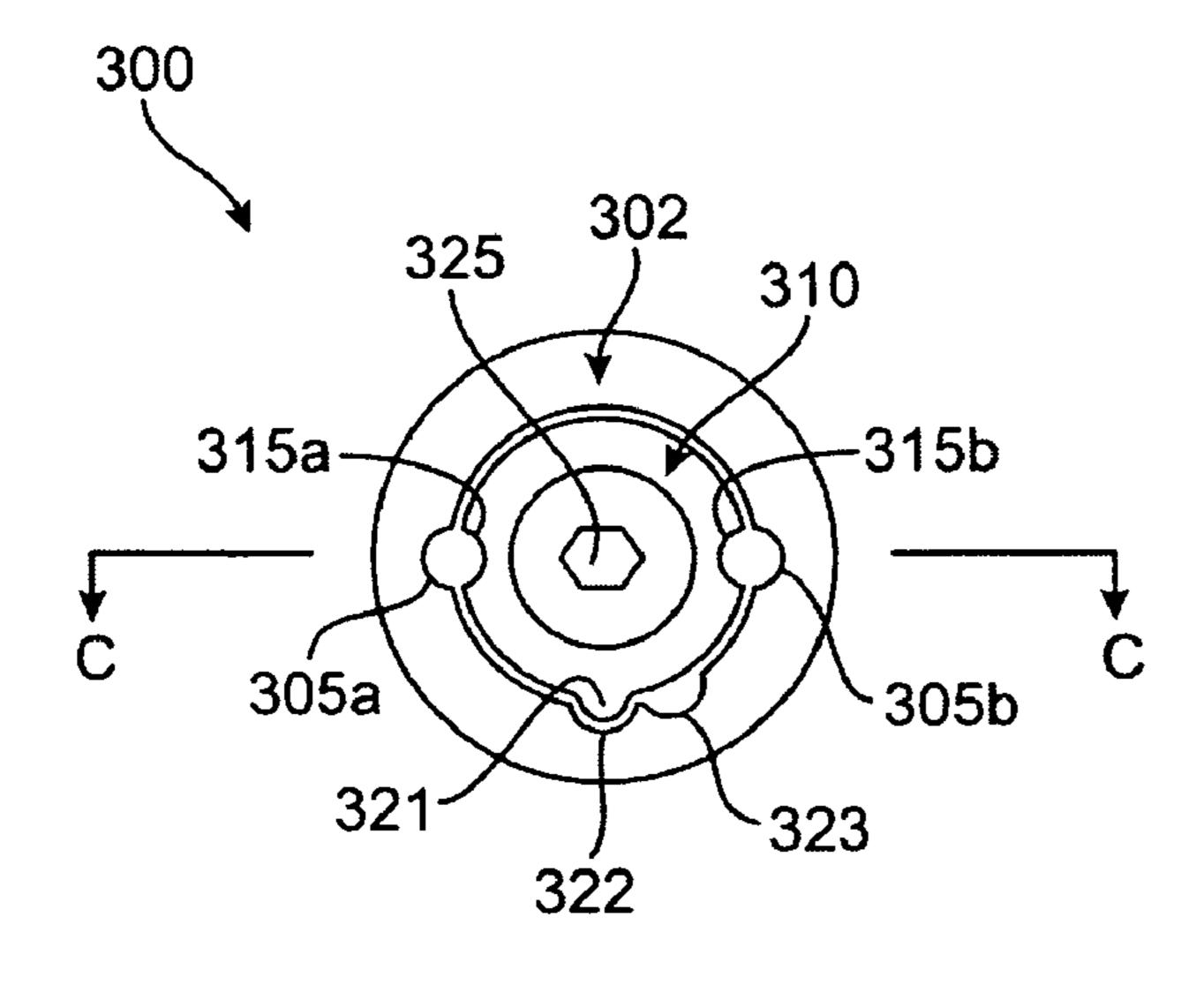


FIG. 15A

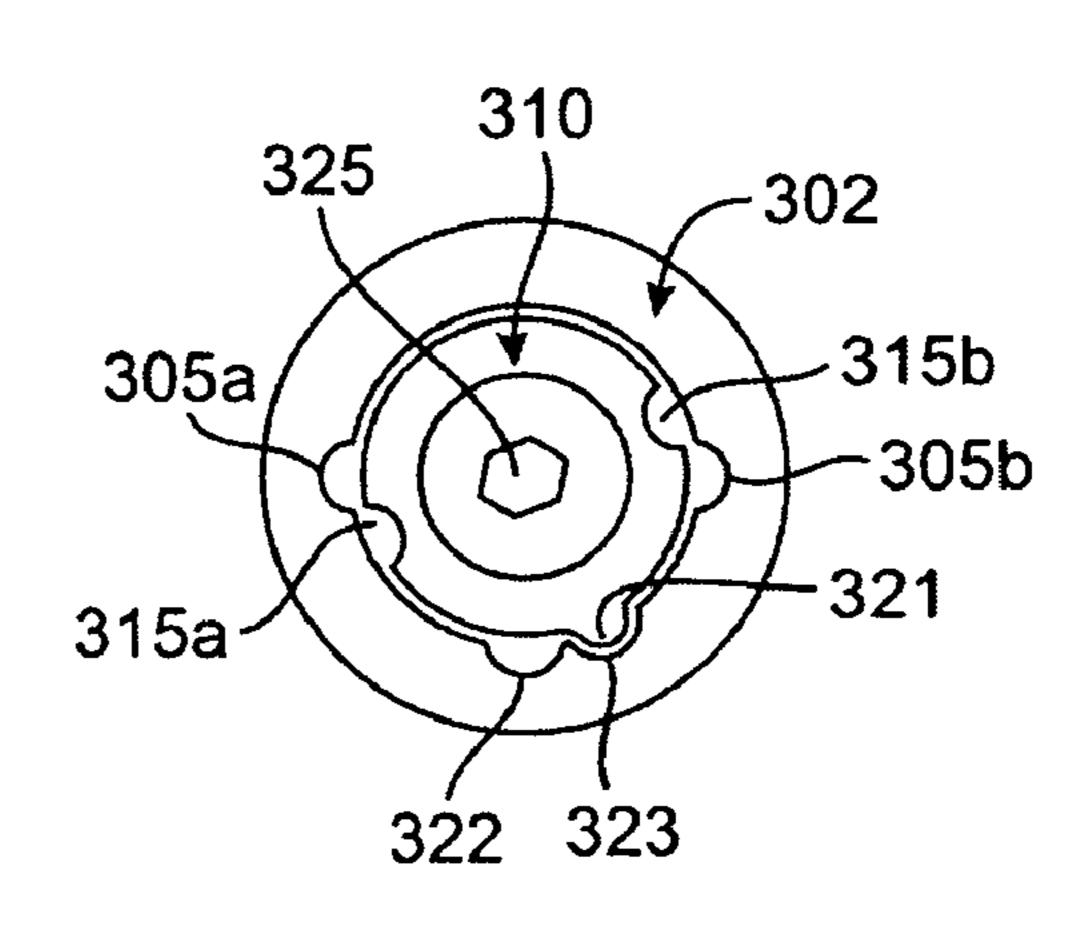


FIG. 15B

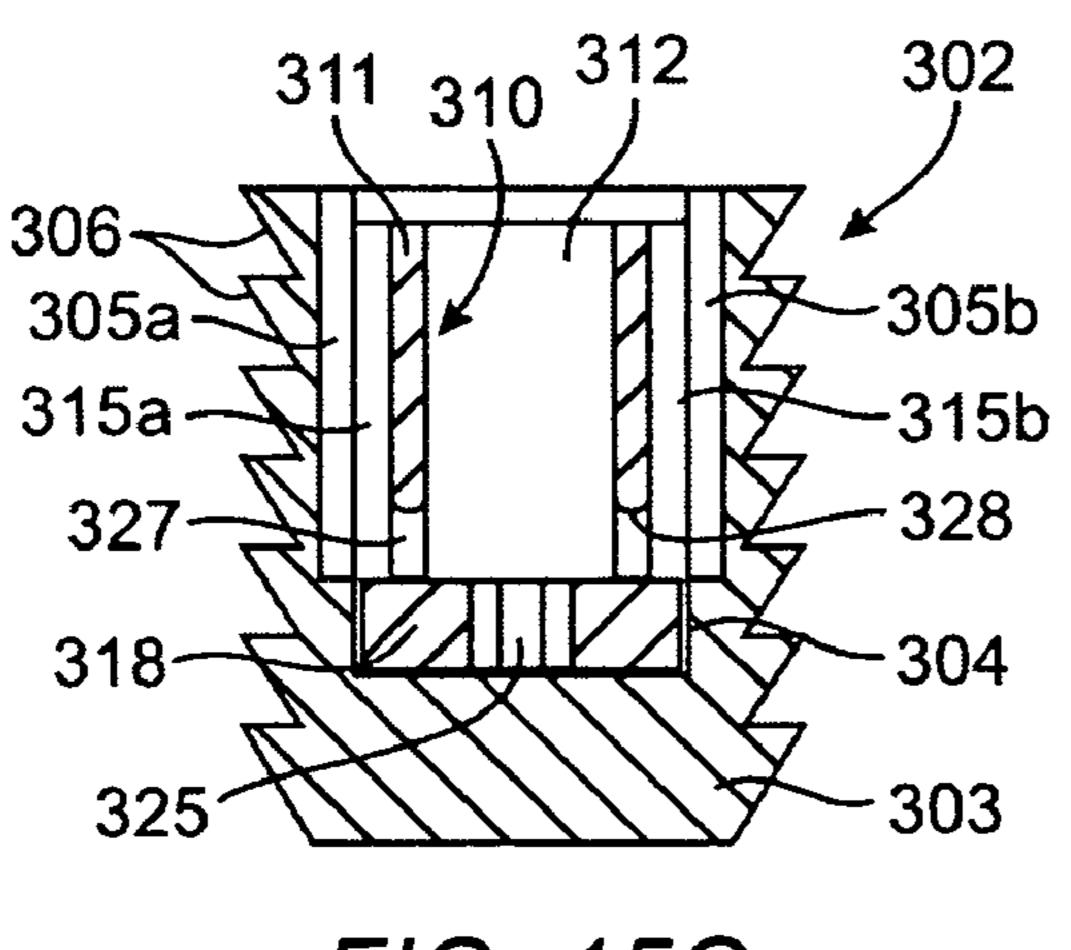


FIG. 15C

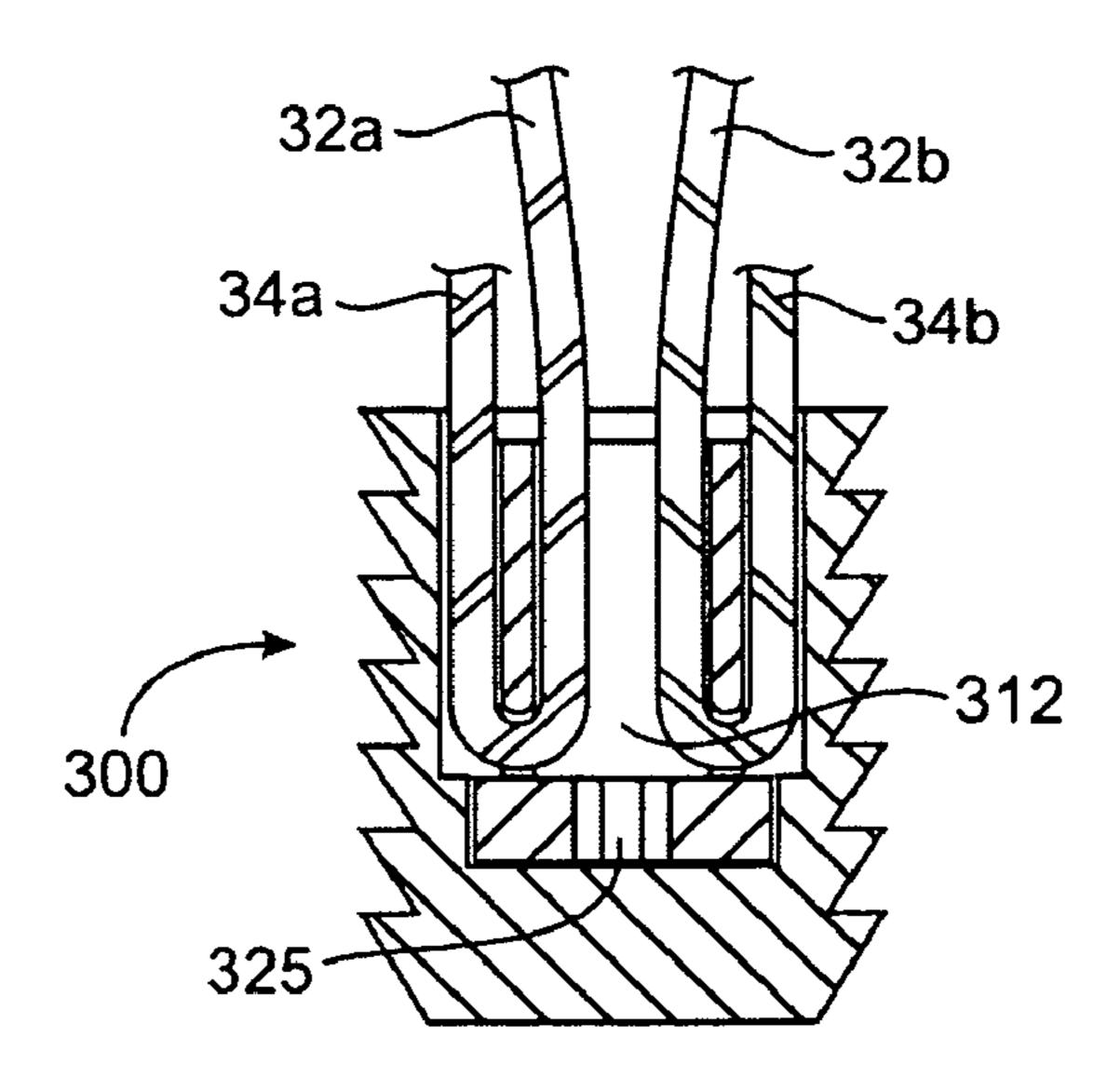


FIG. 16

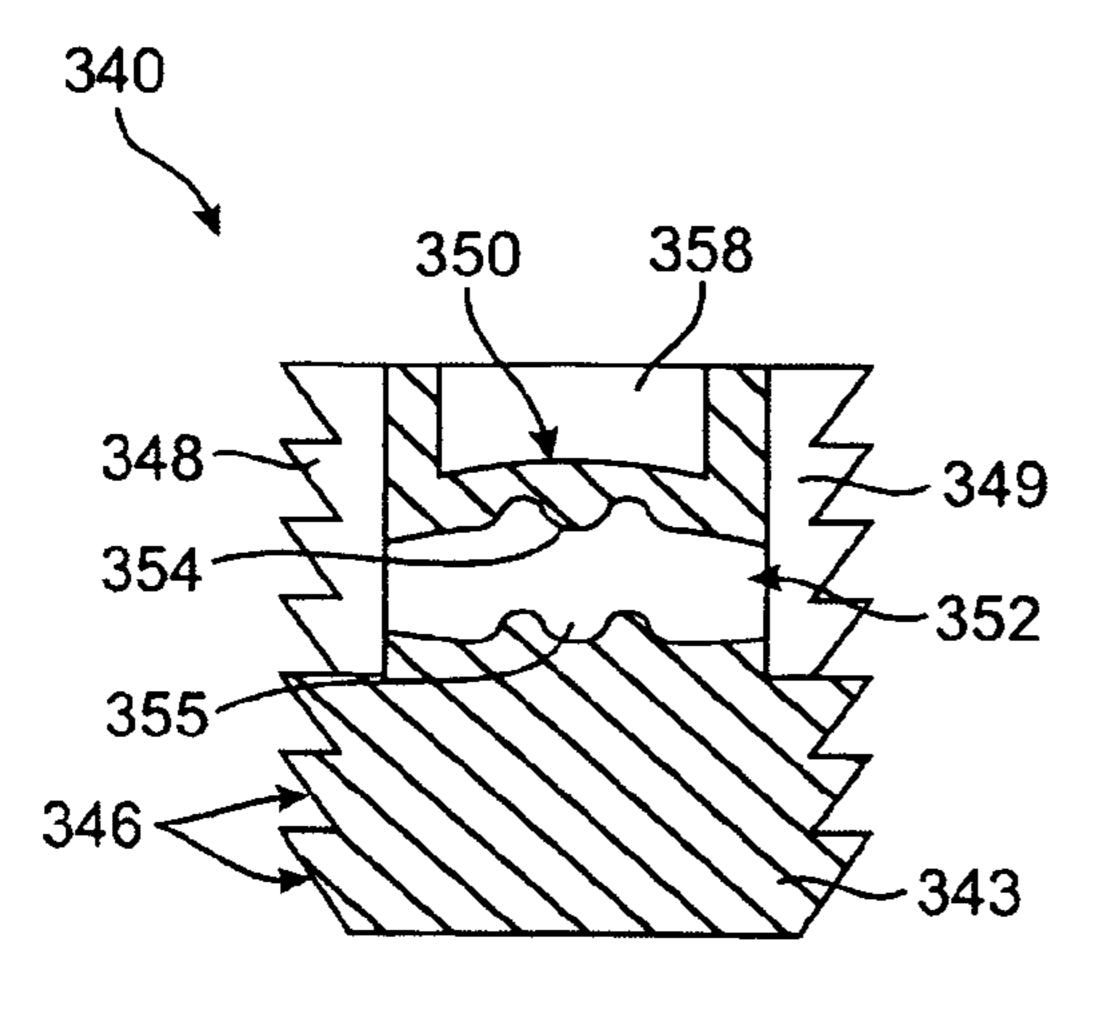
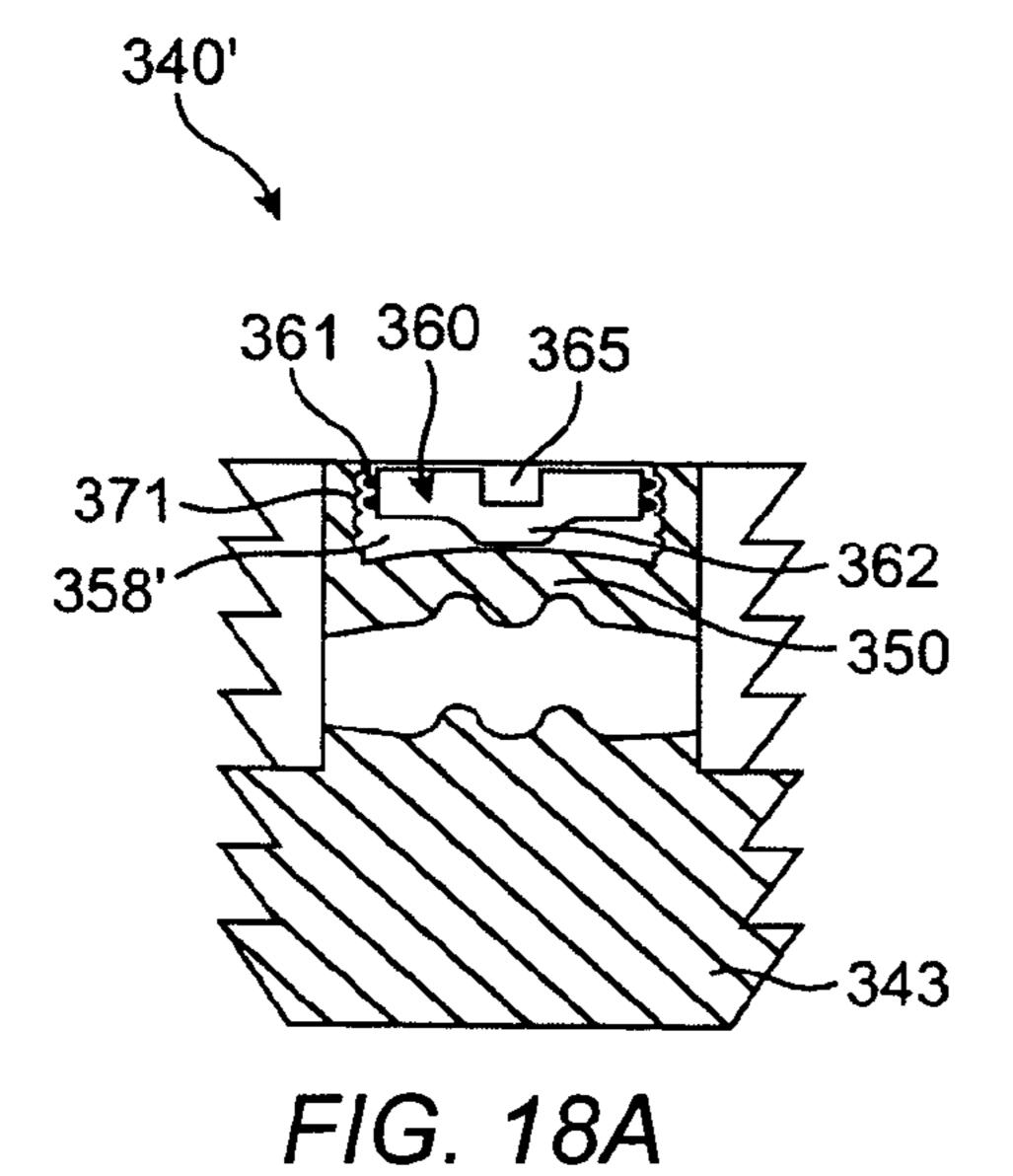


FIG. 17A



391 383a 395 390 355" 382 352"

358"

346

380

340"

FIG. 19A

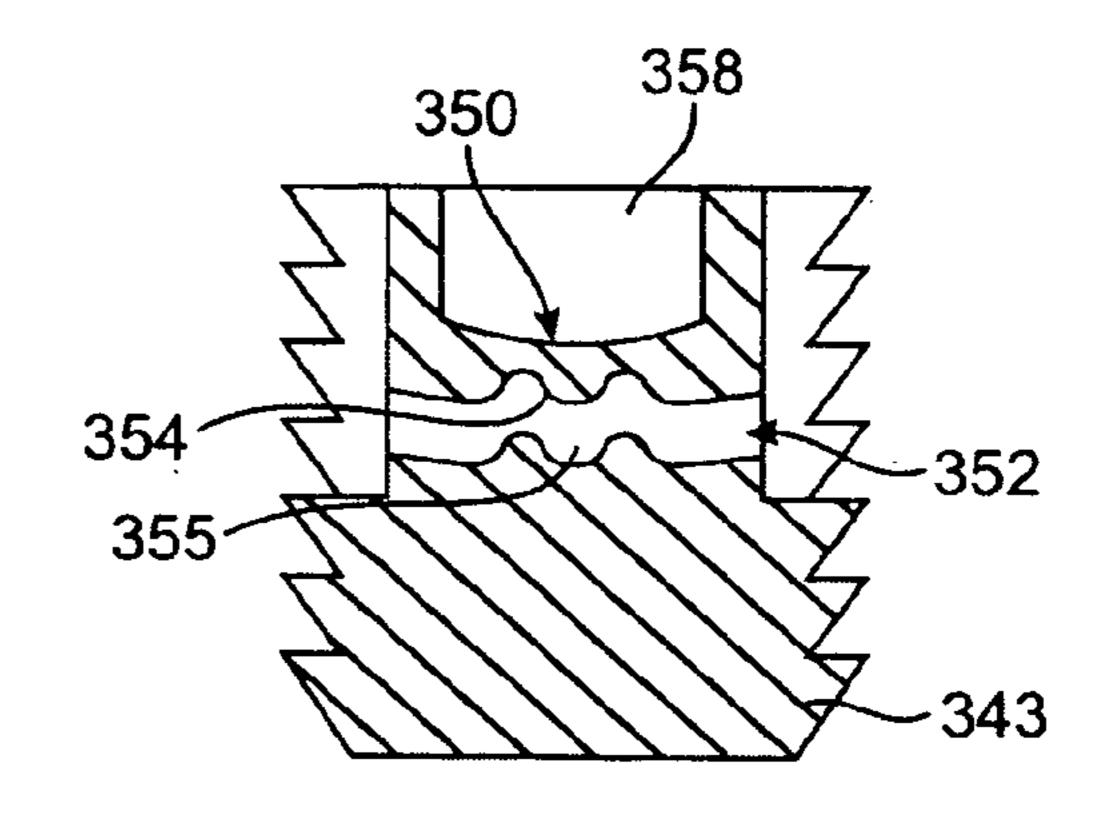


FIG. 17B

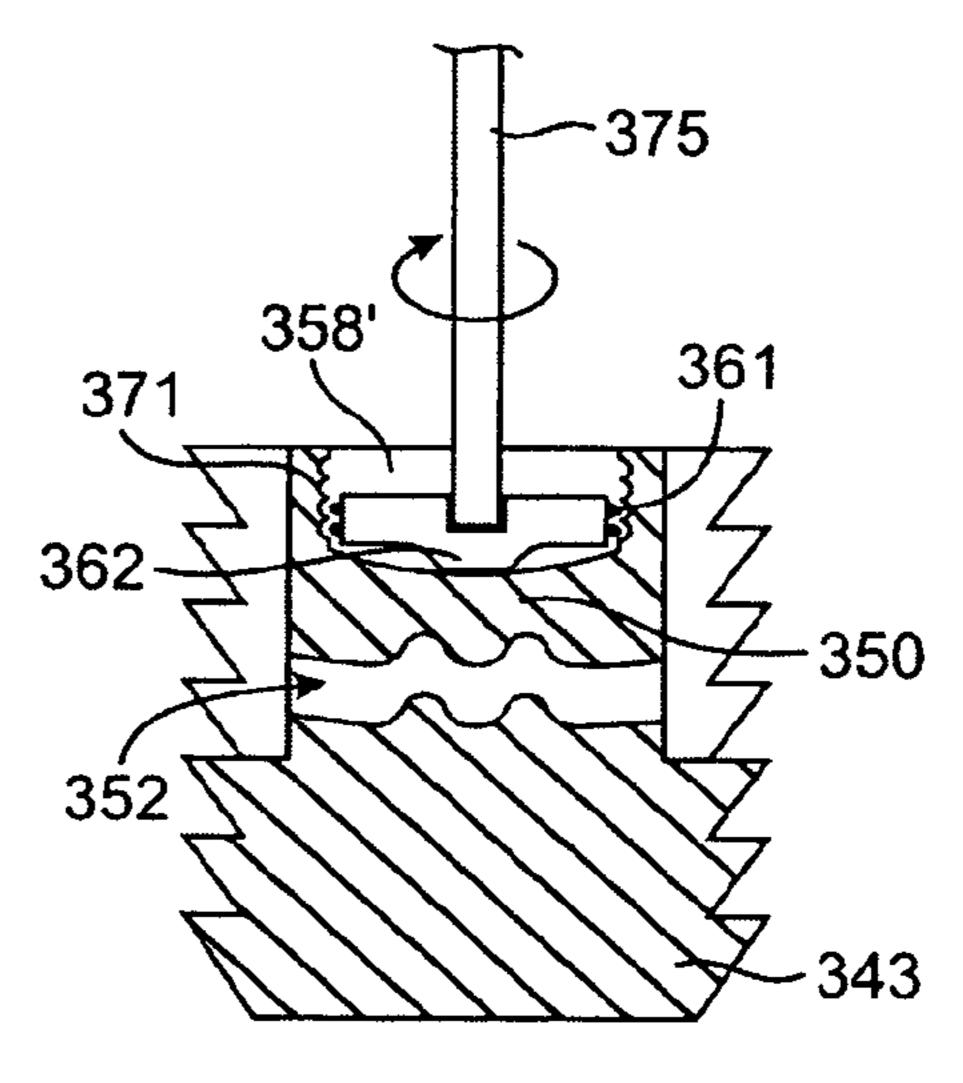


FIG. 18B

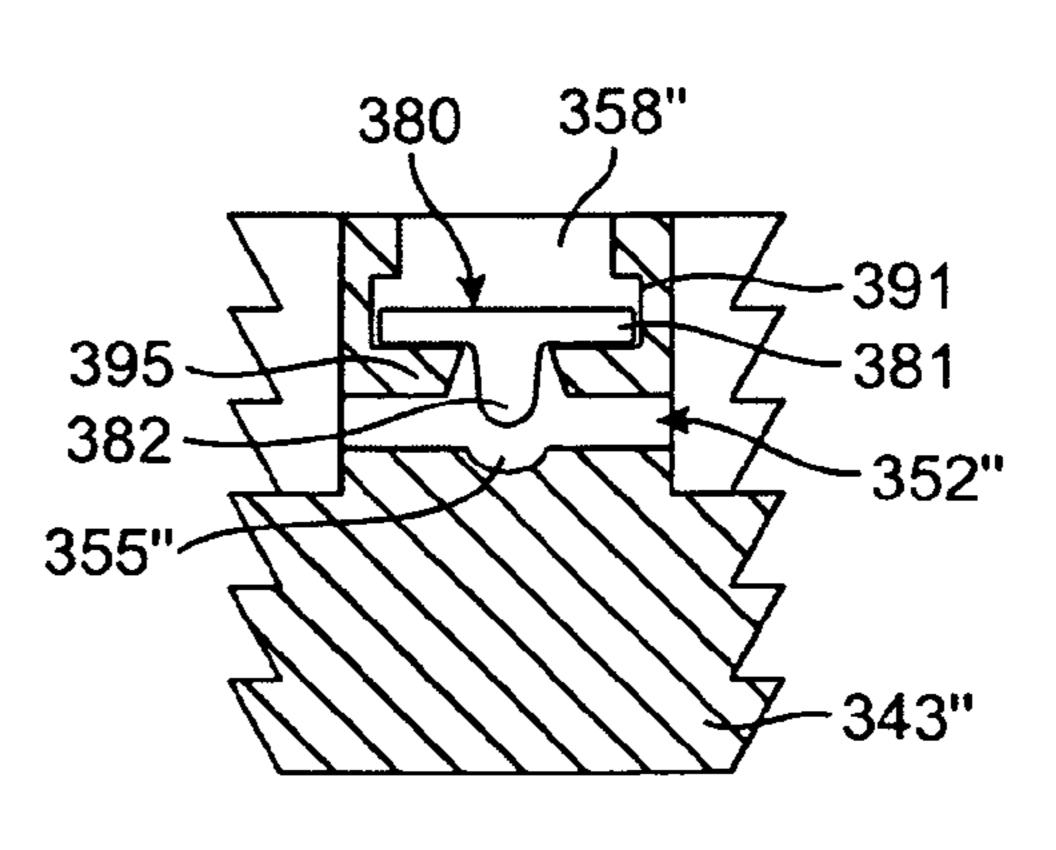
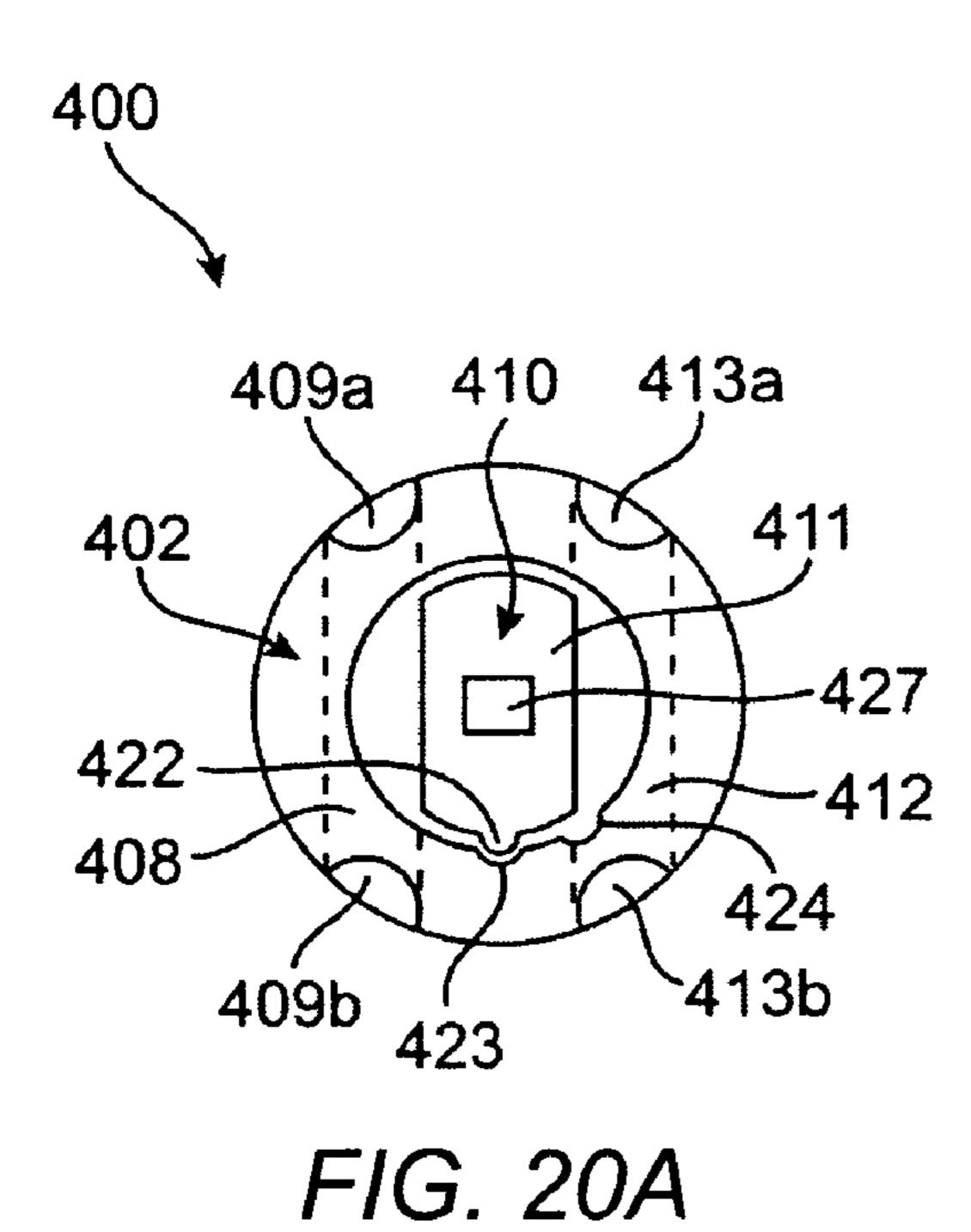


FIG. 19B



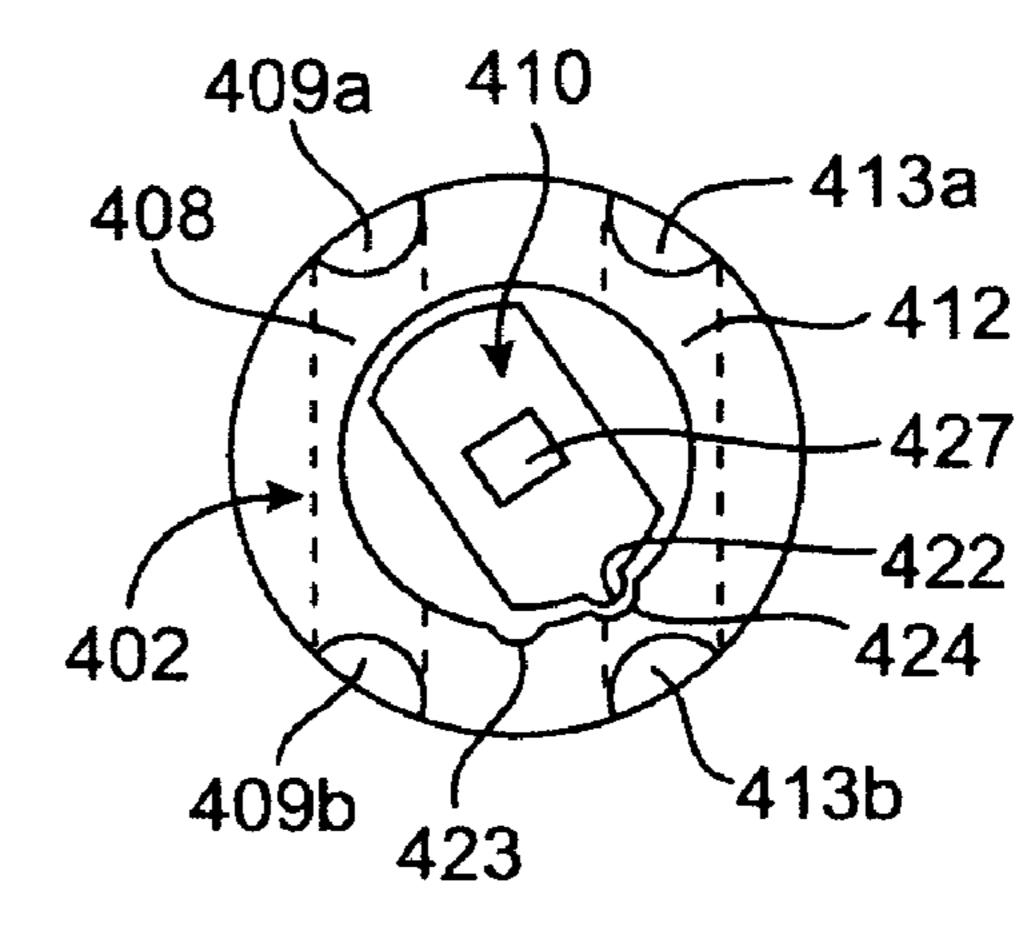
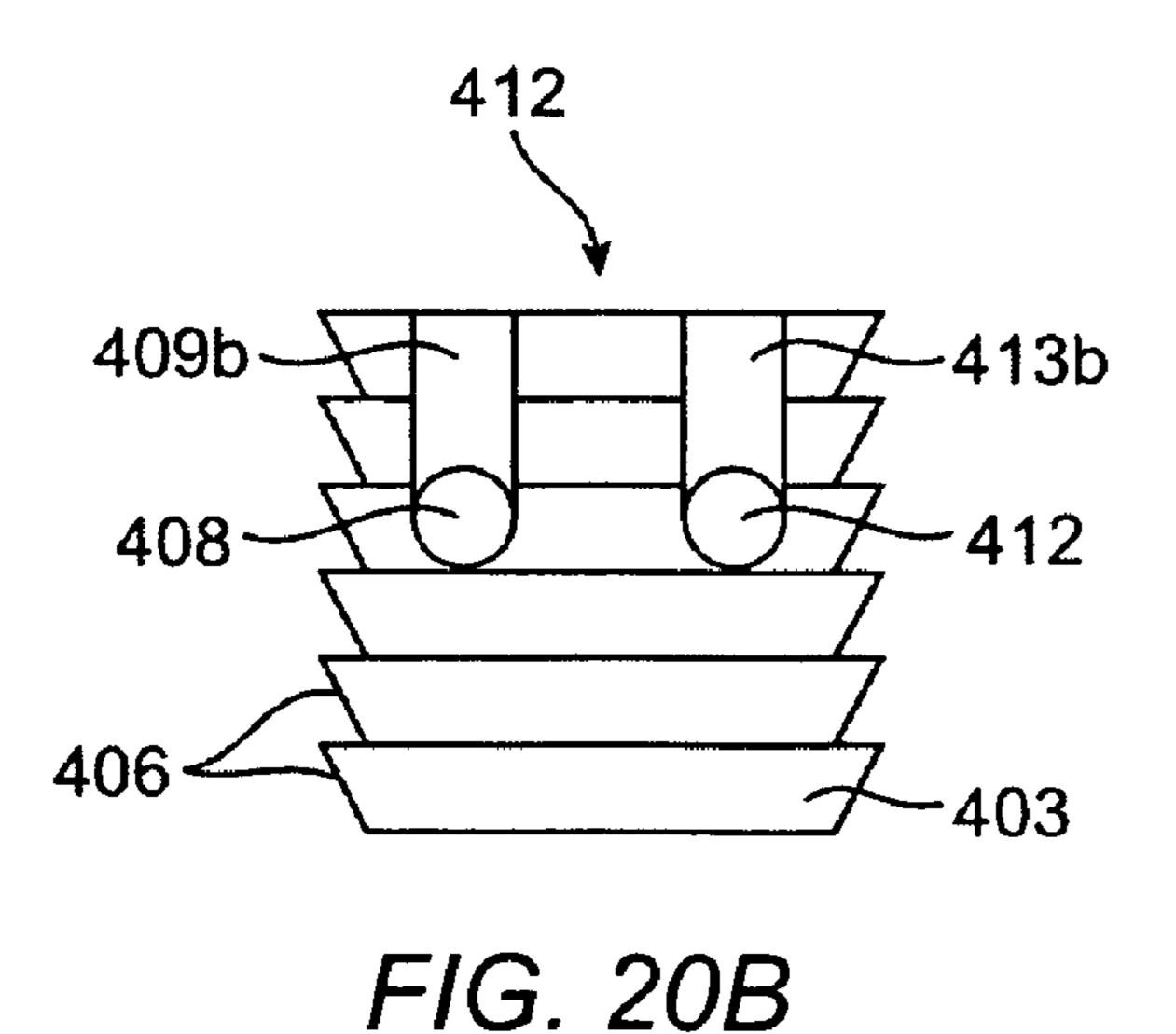


FIG. 21A



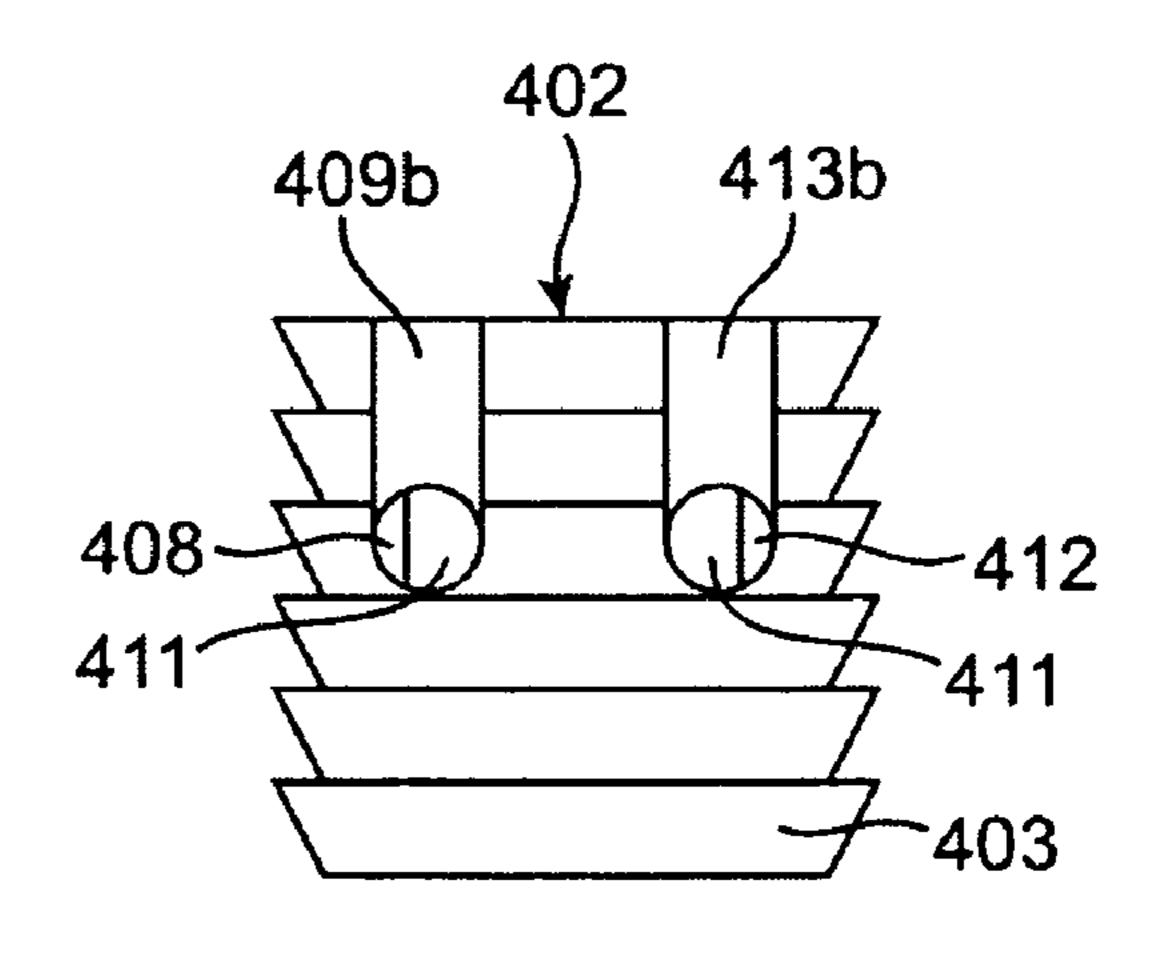
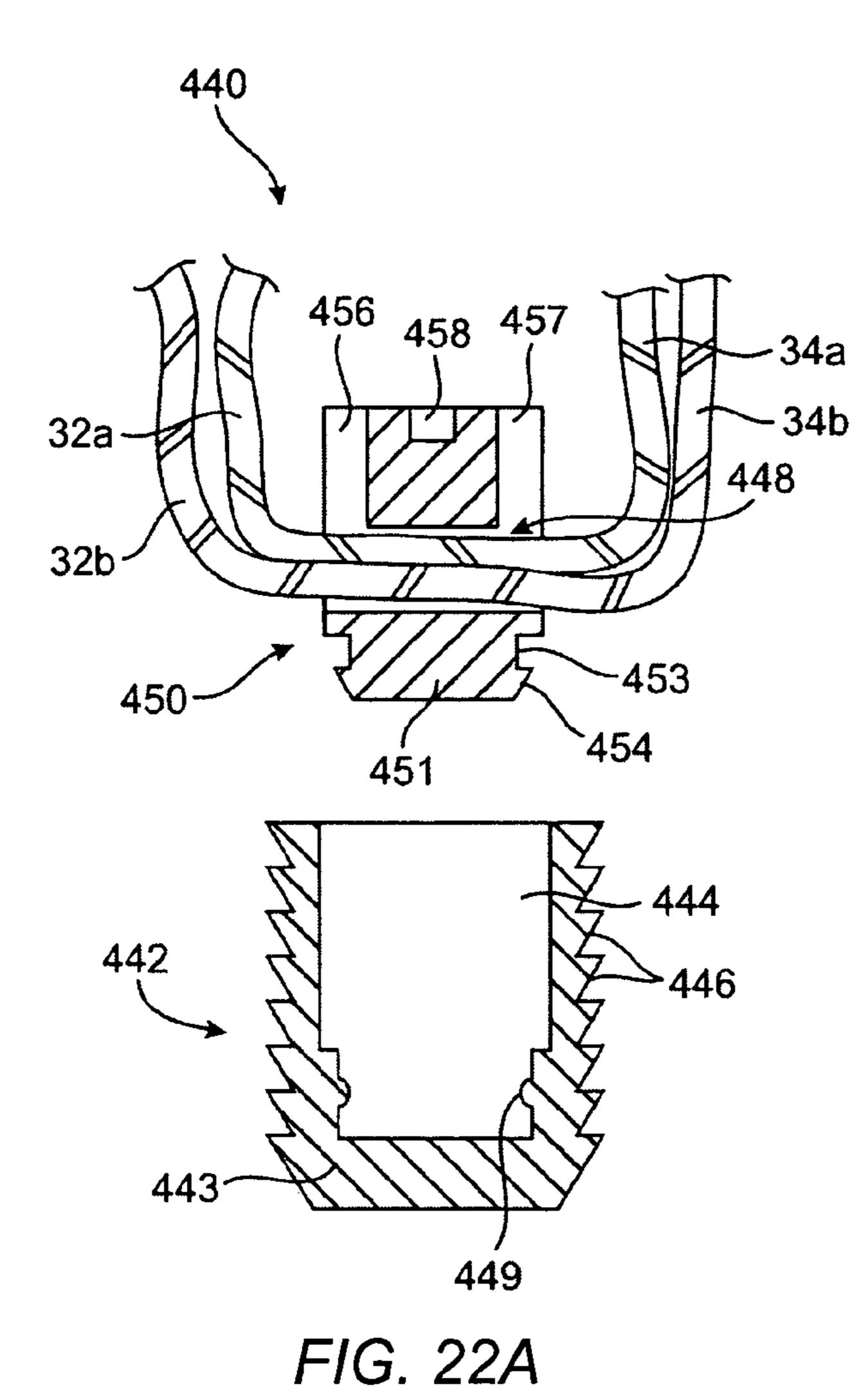


FIG. 21B



32a 34b **∖**34a 458 ⁻448 453 ⁴⁴⁹ 450 **-442**

FIG. 22B

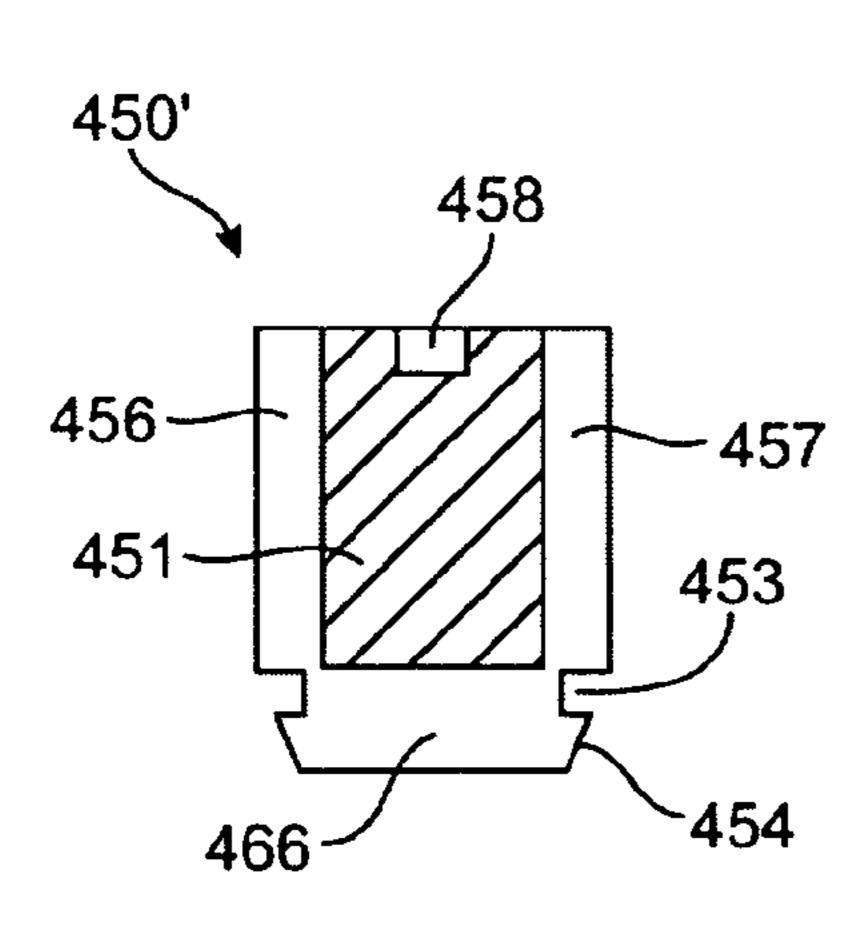


FIG. 23A

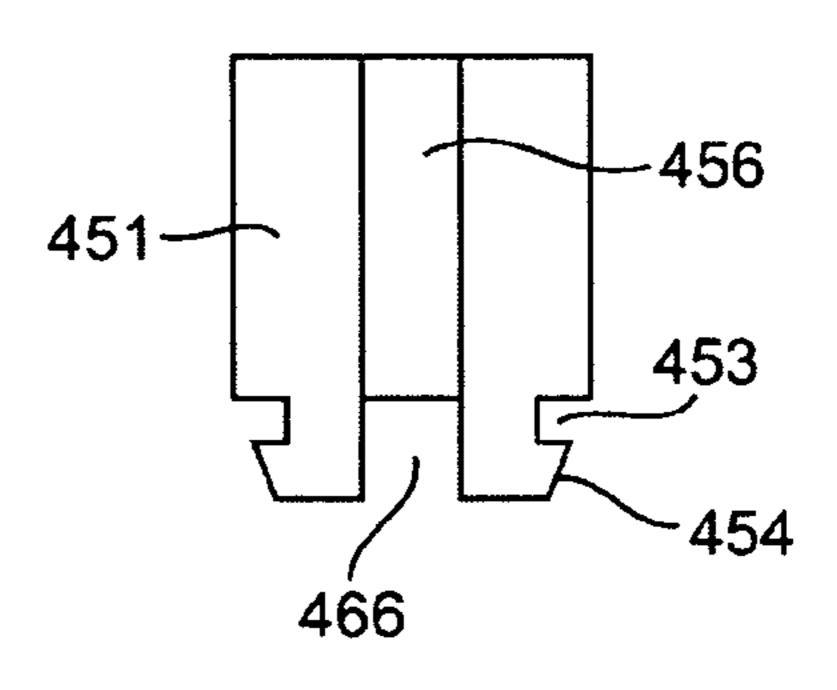


FIG. 23B

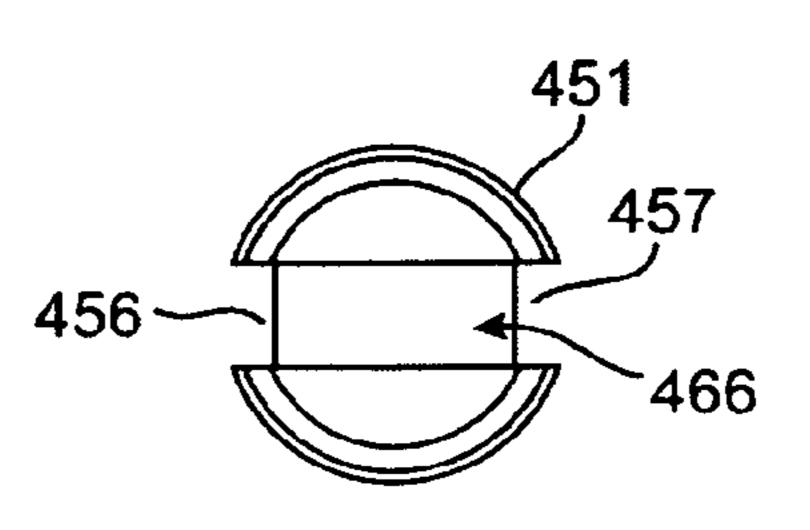
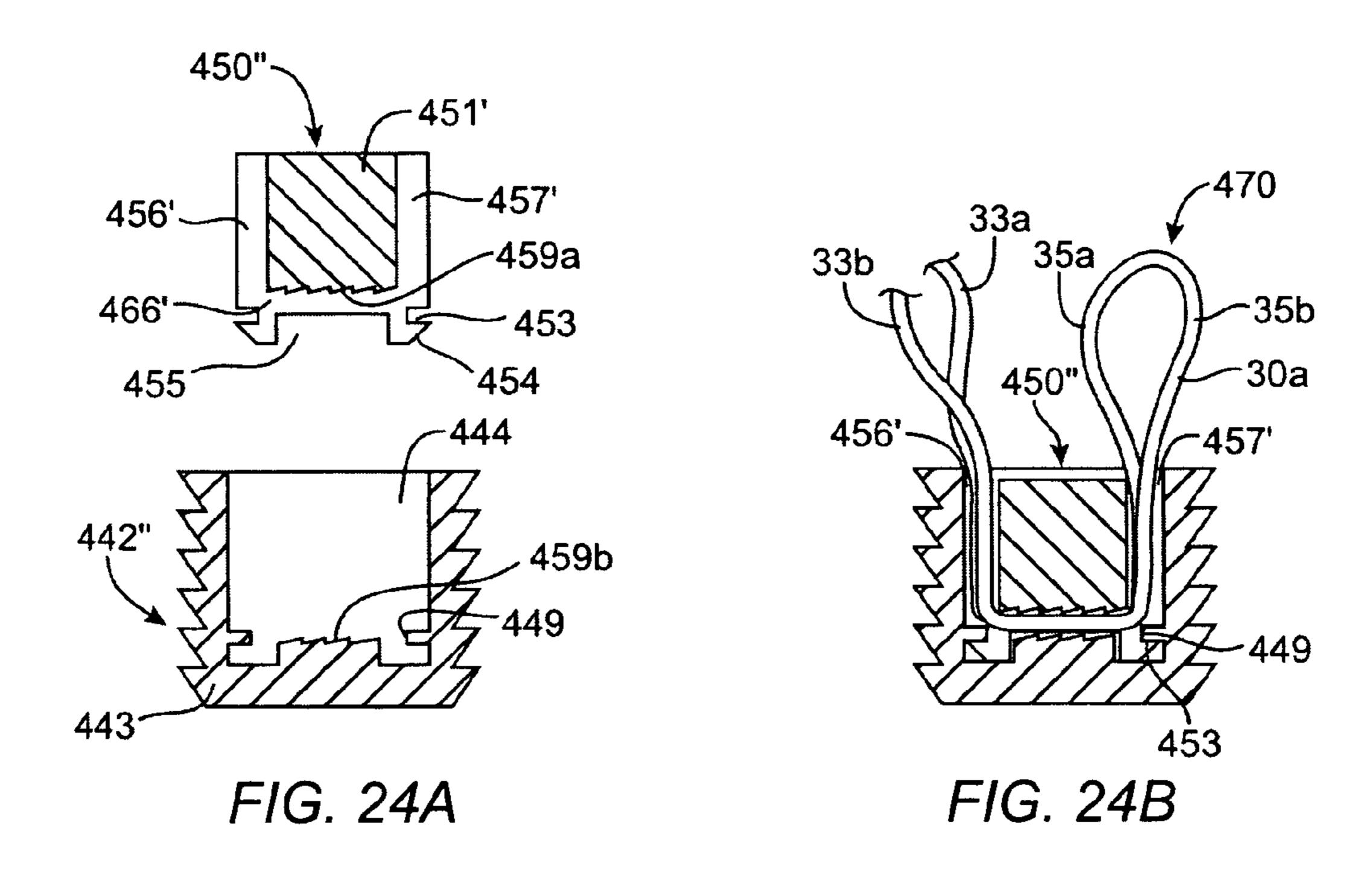
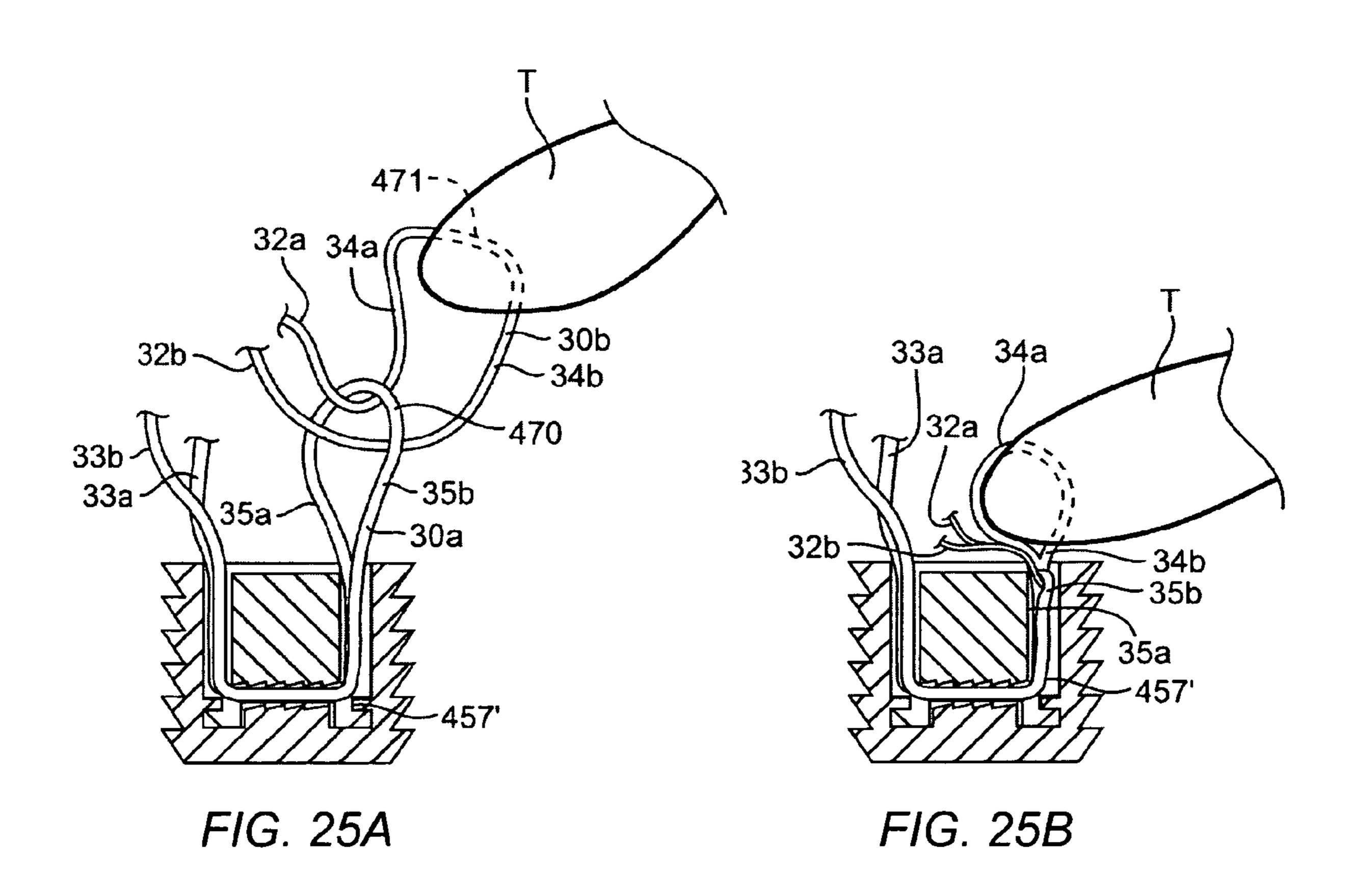


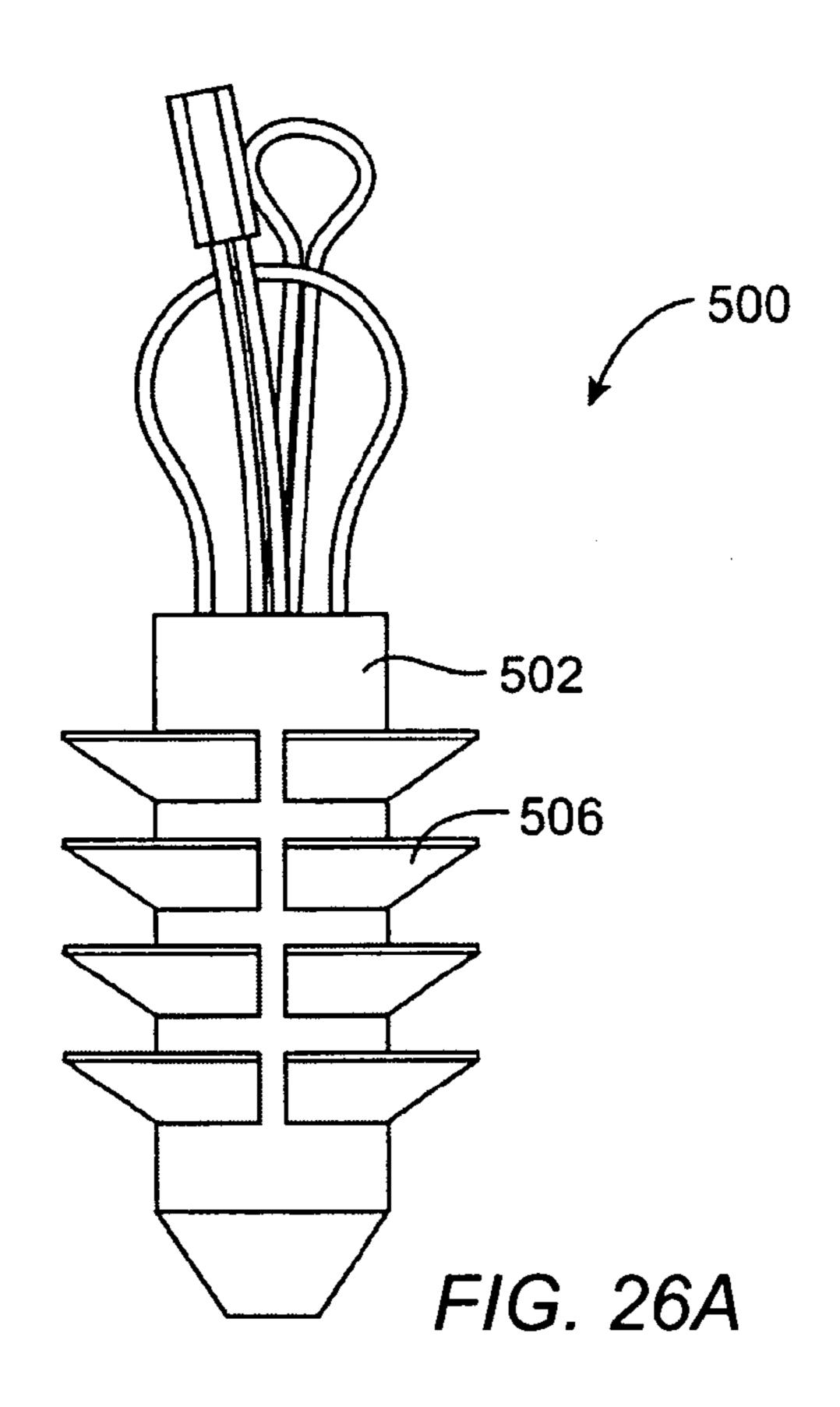
FIG. 23C

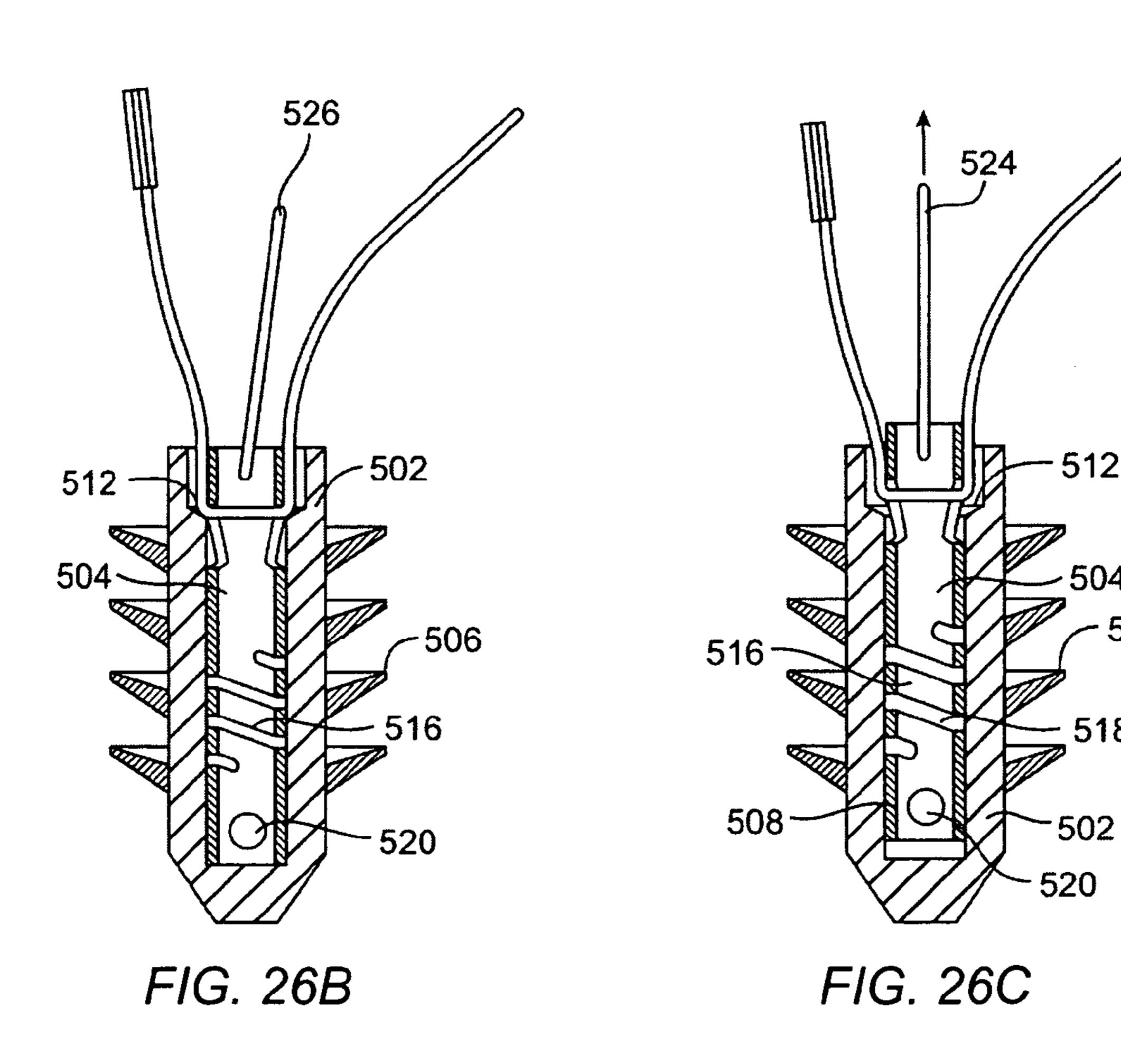




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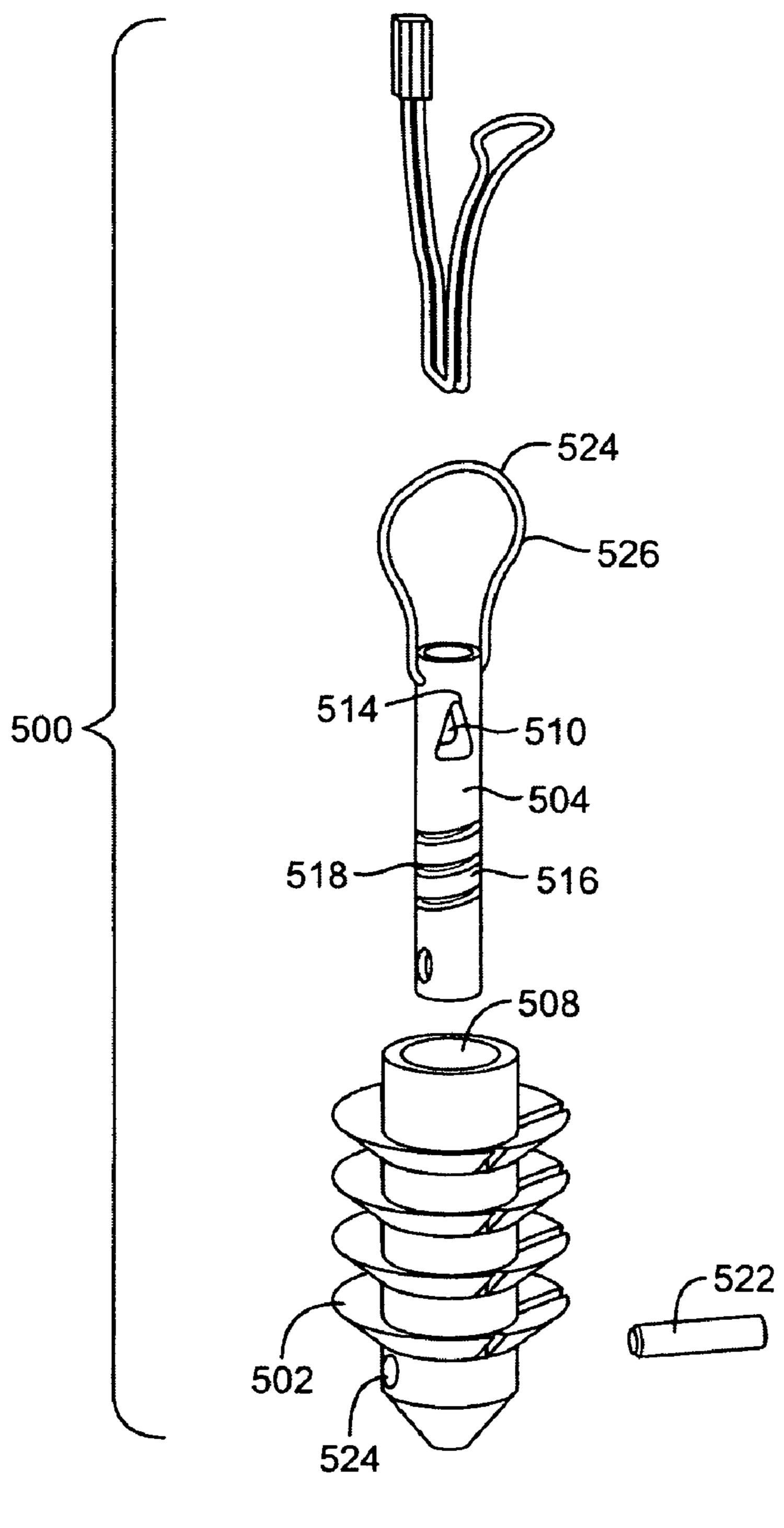
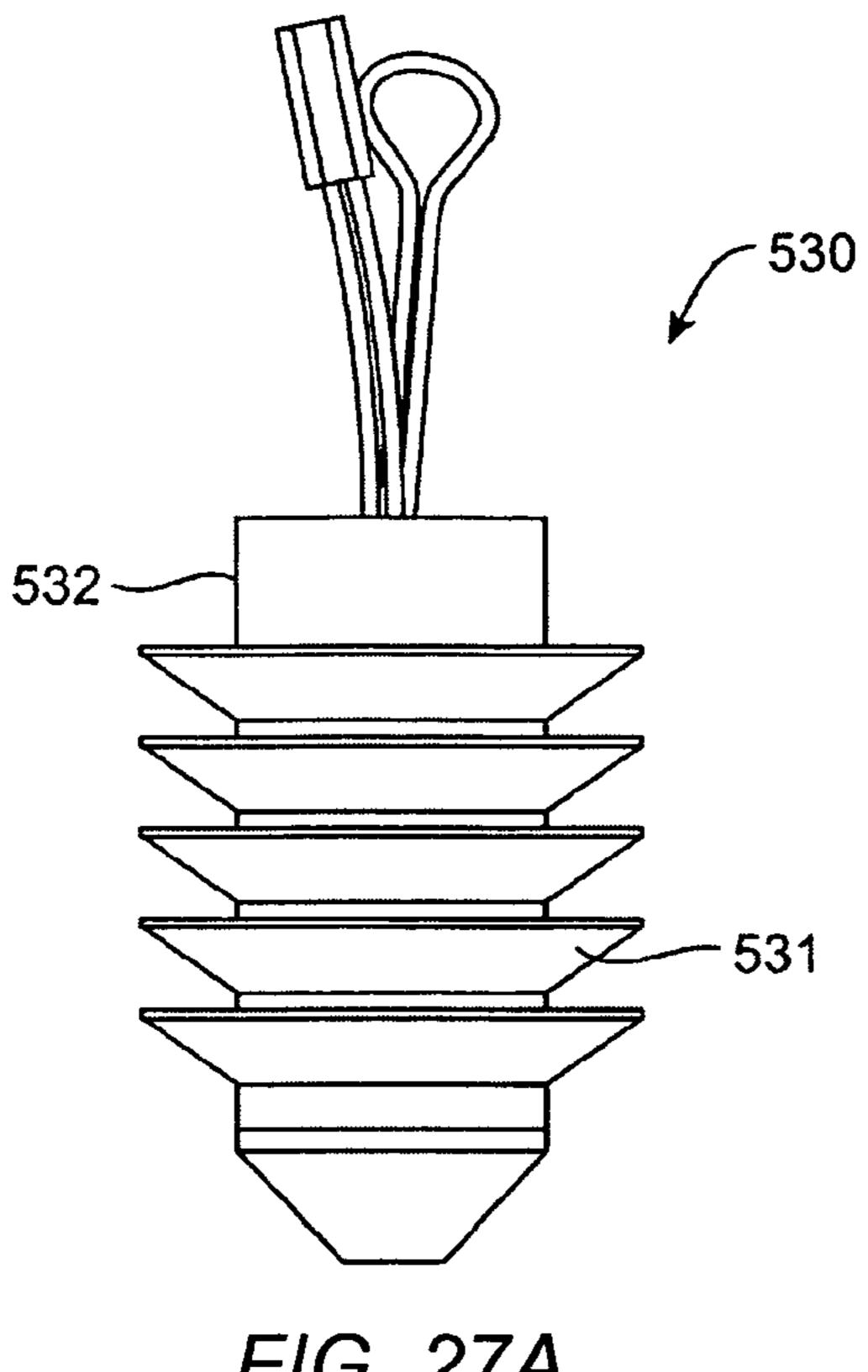


FIG. 26D





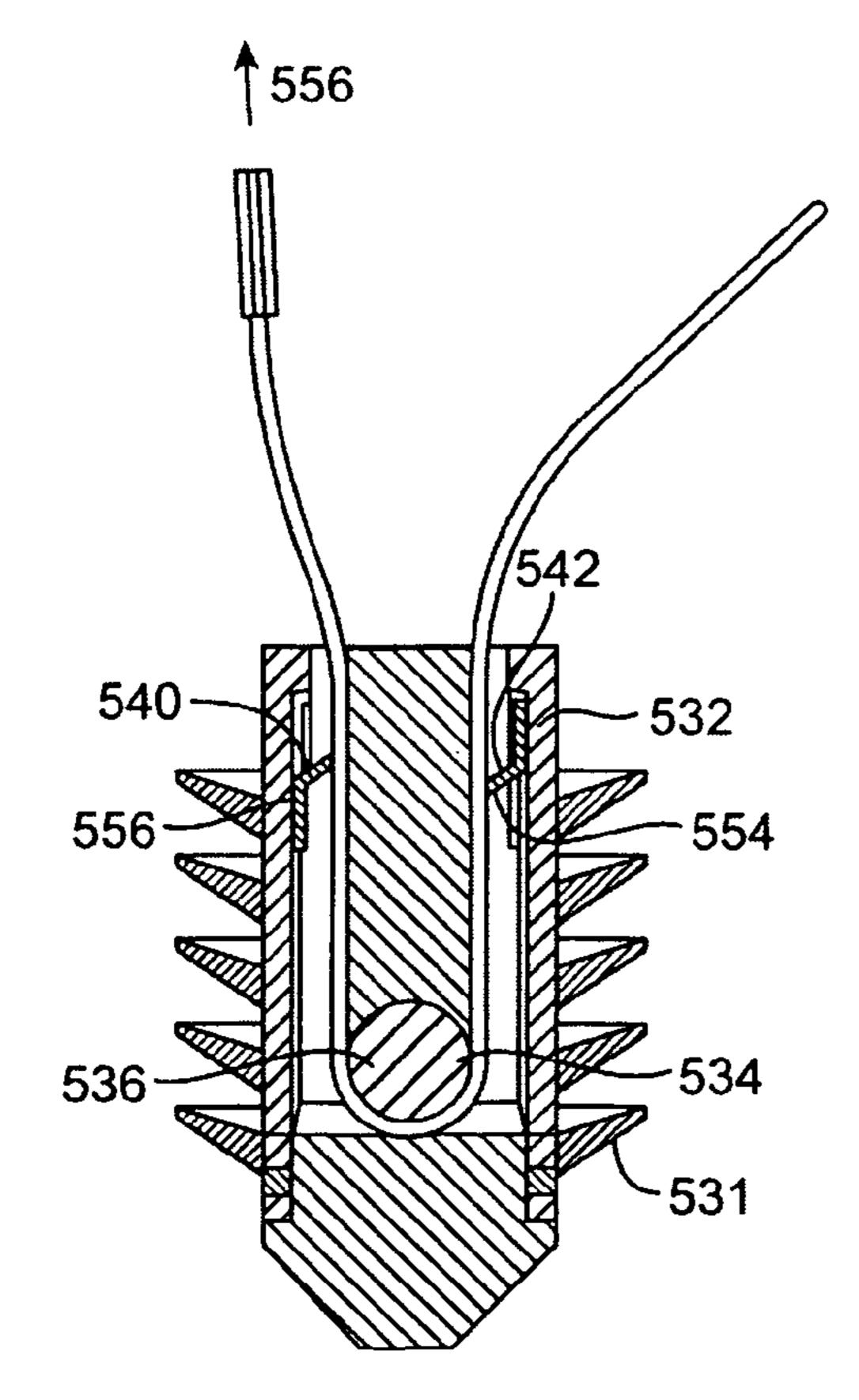


FIG. 27B

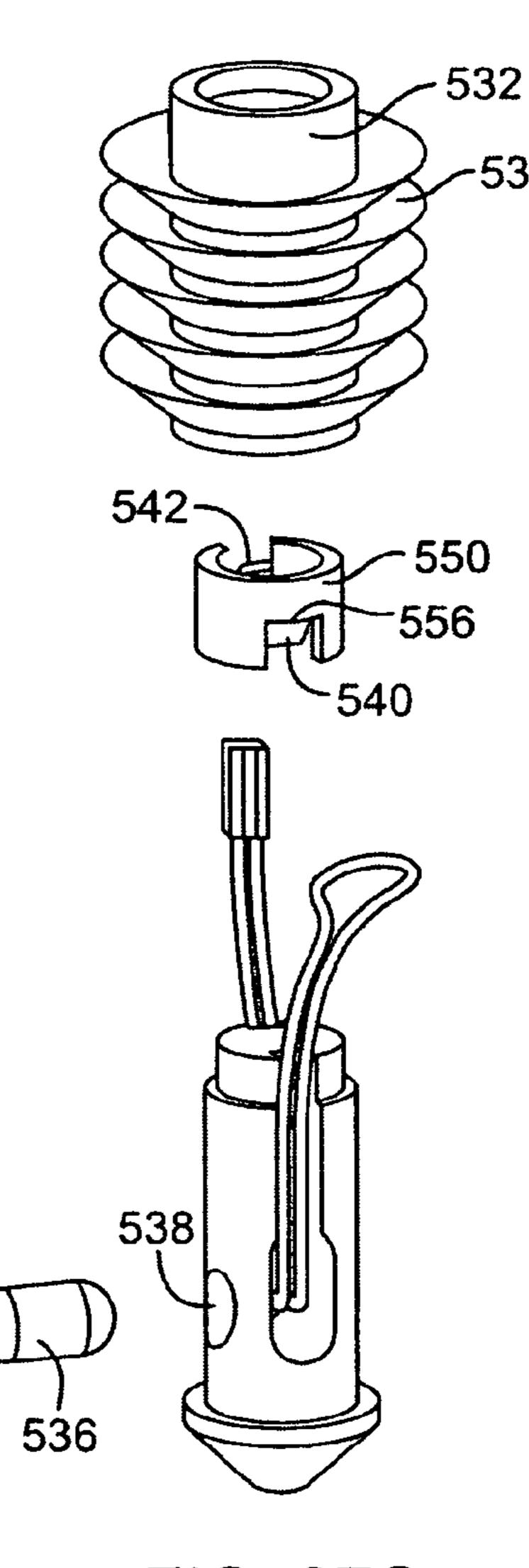
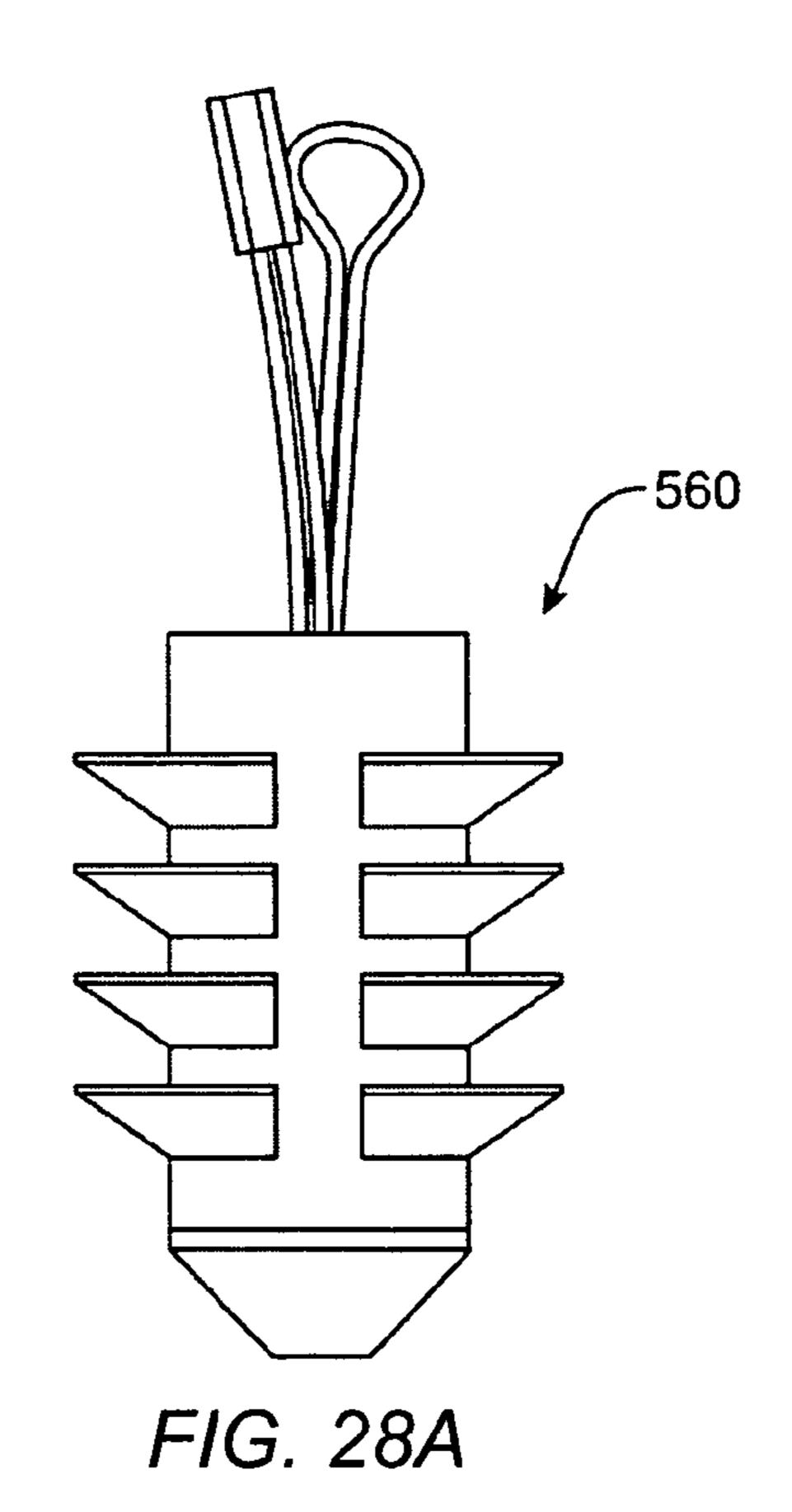
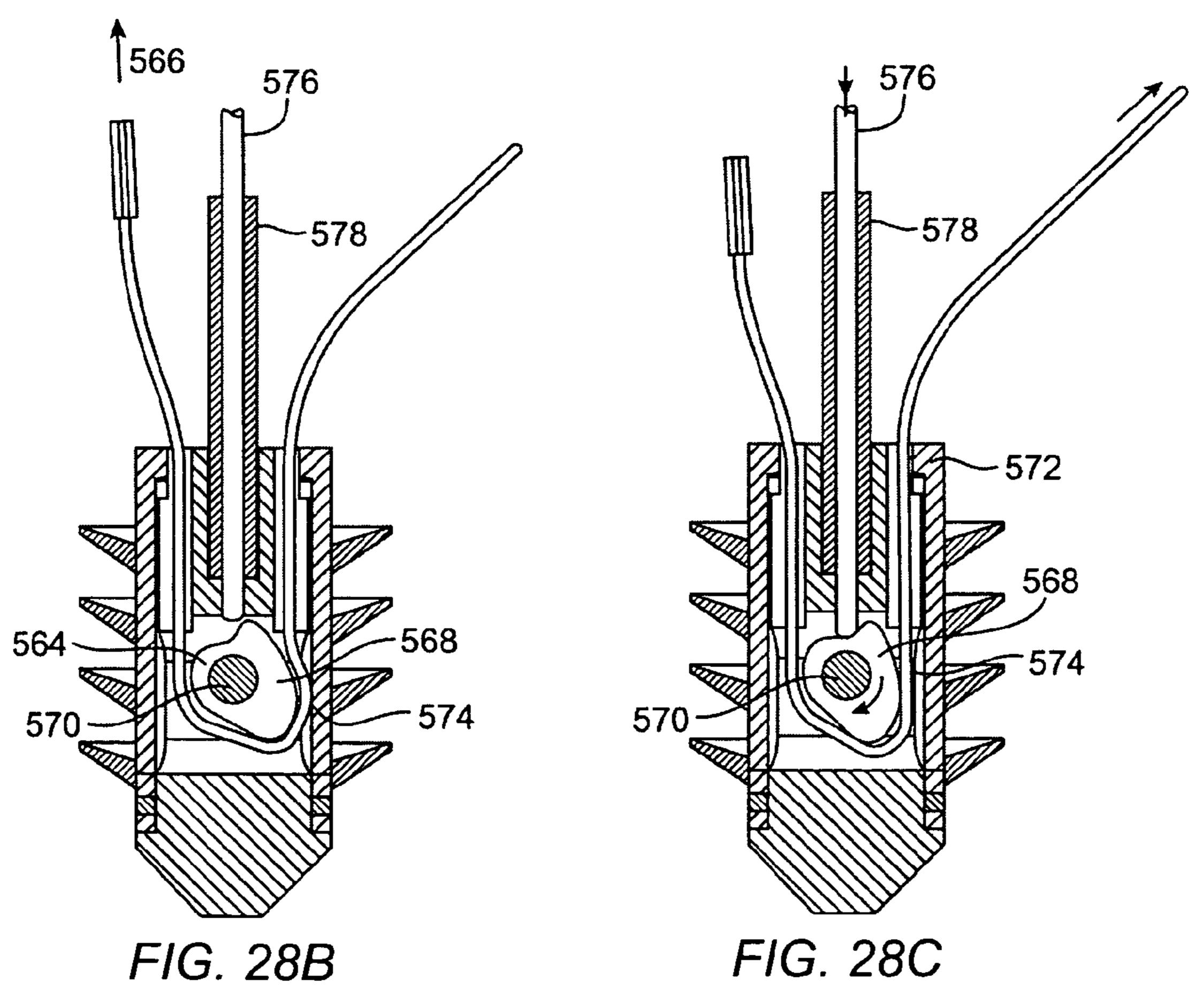


FIG. 27C





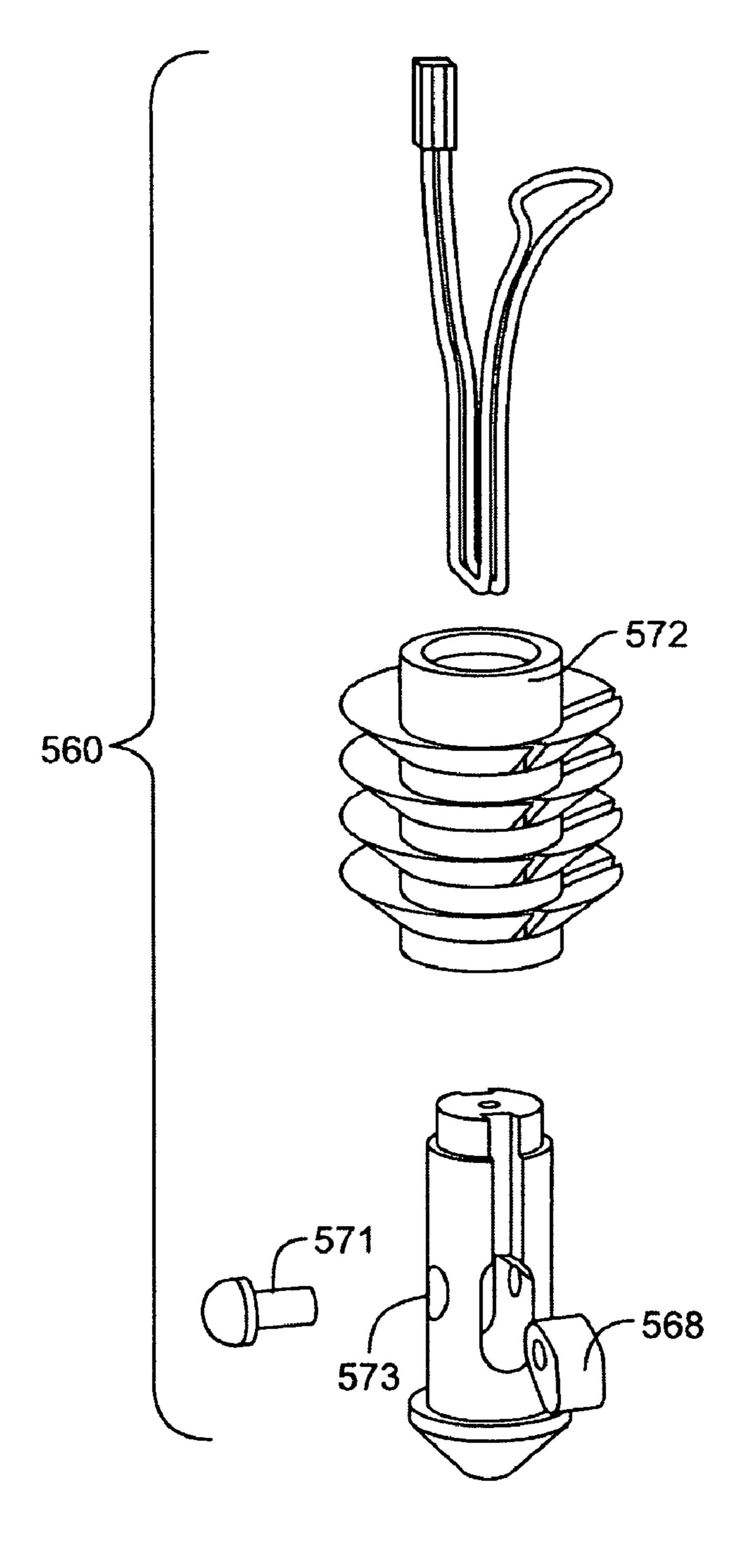


FIG. 28D

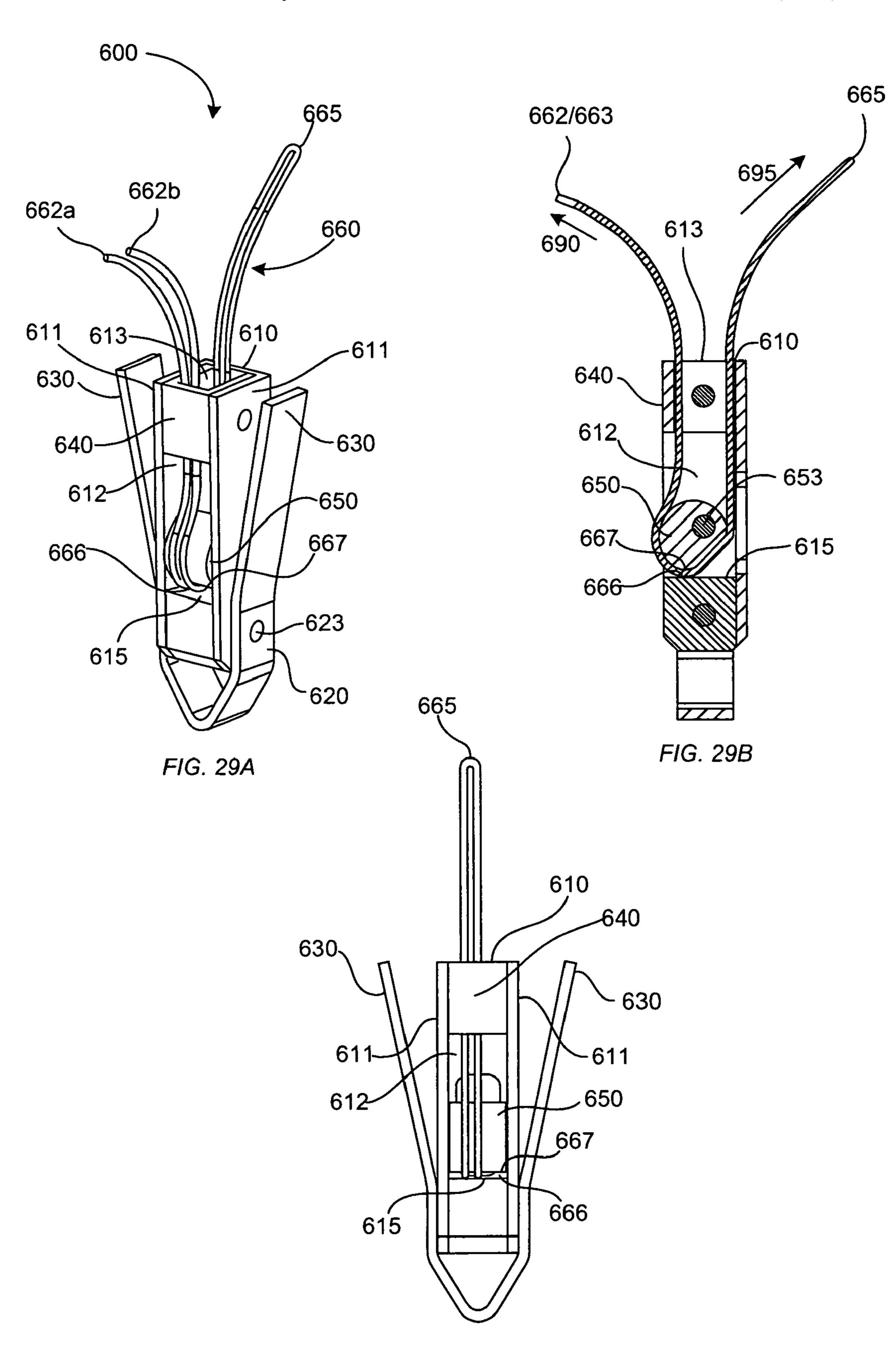
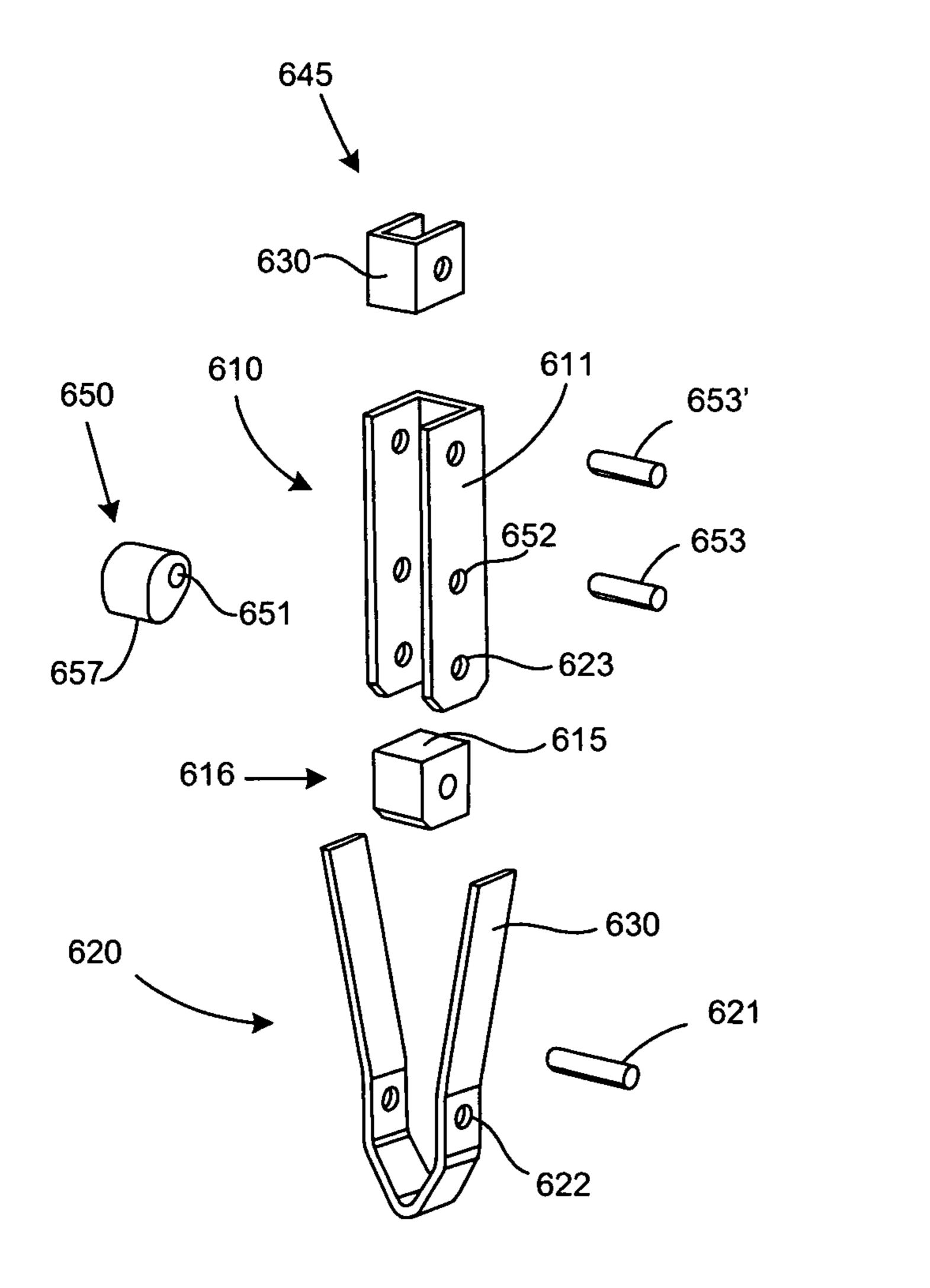


FIG. 29C



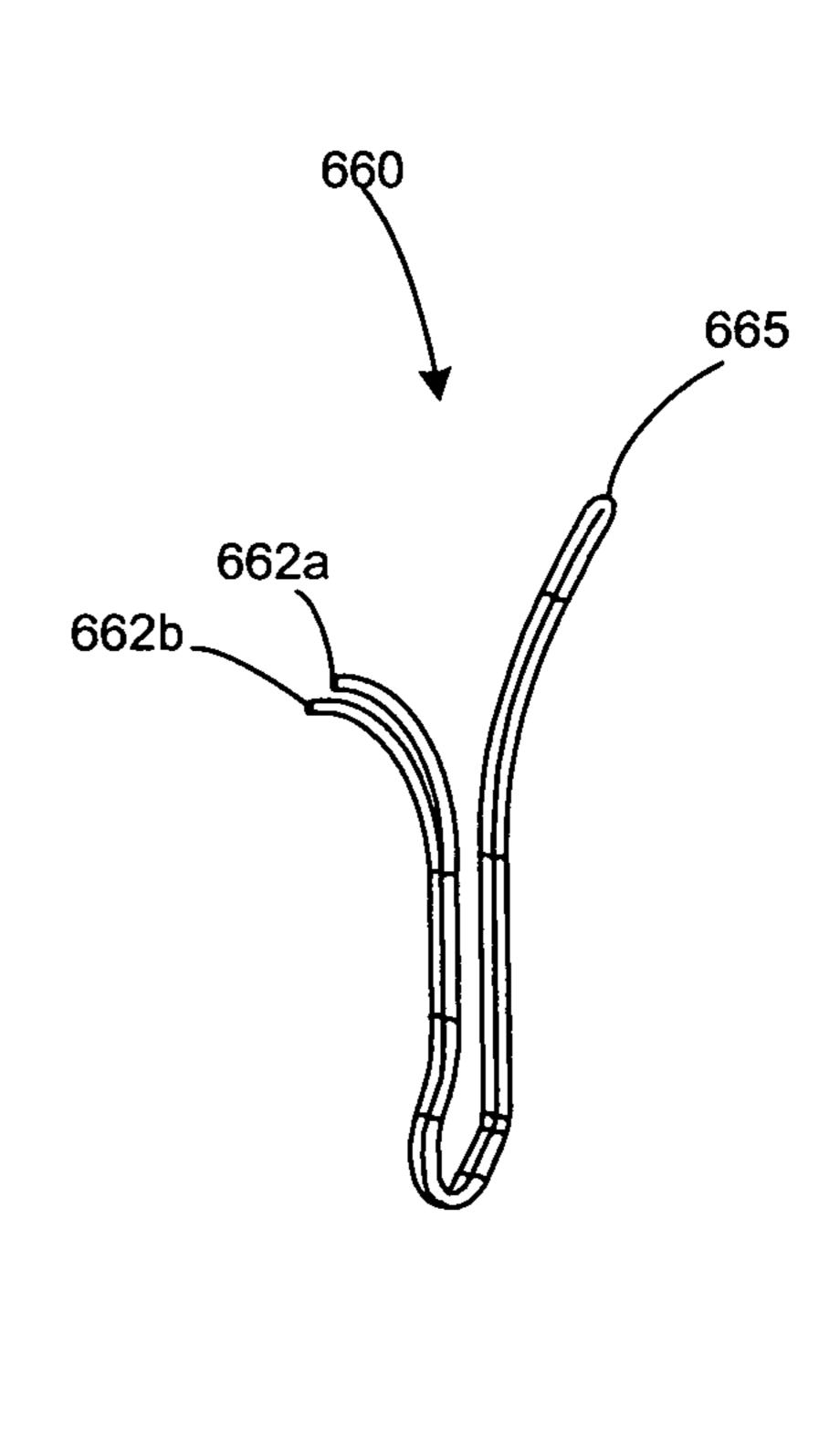


FIG. 29D

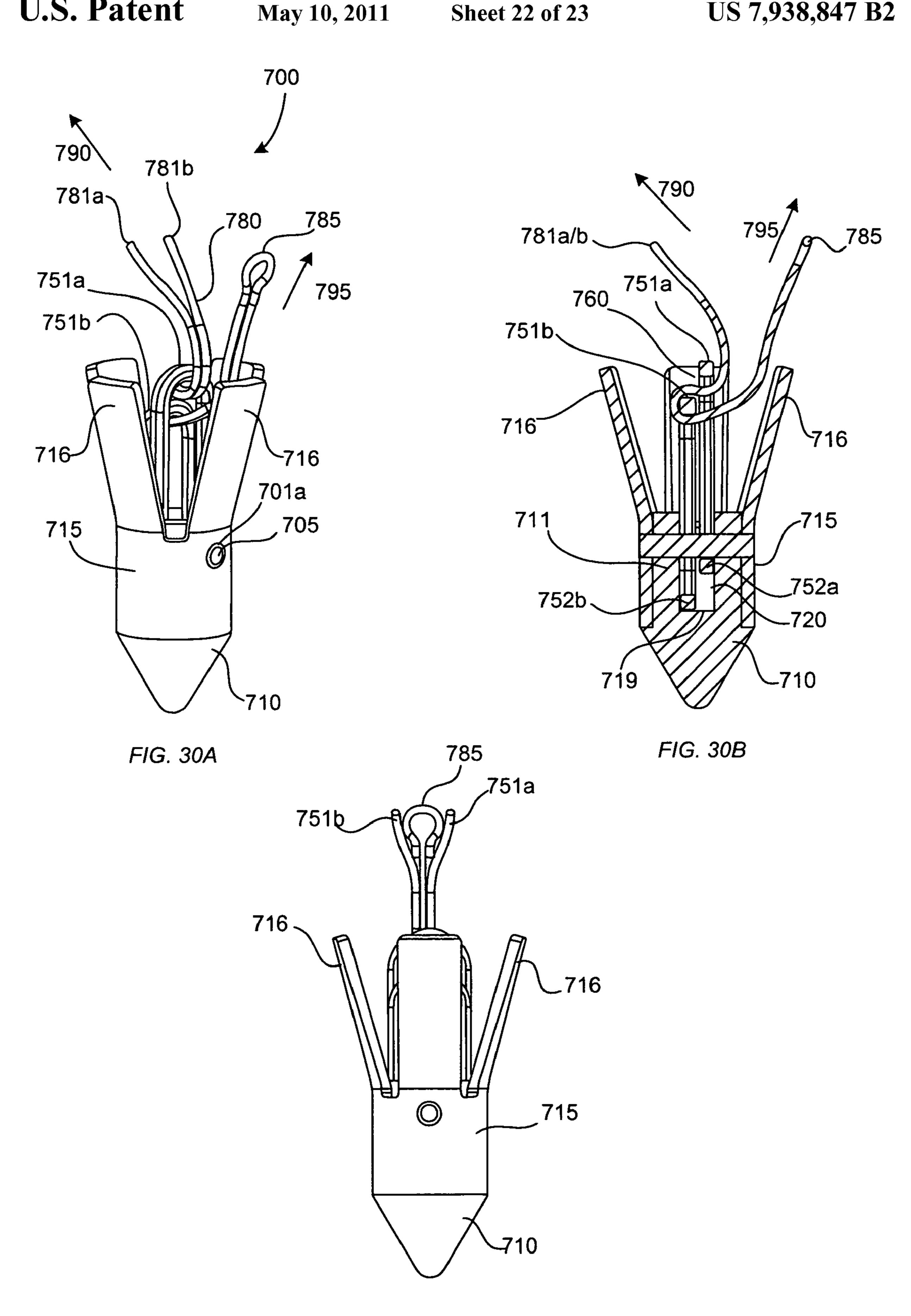


FIG. 30C



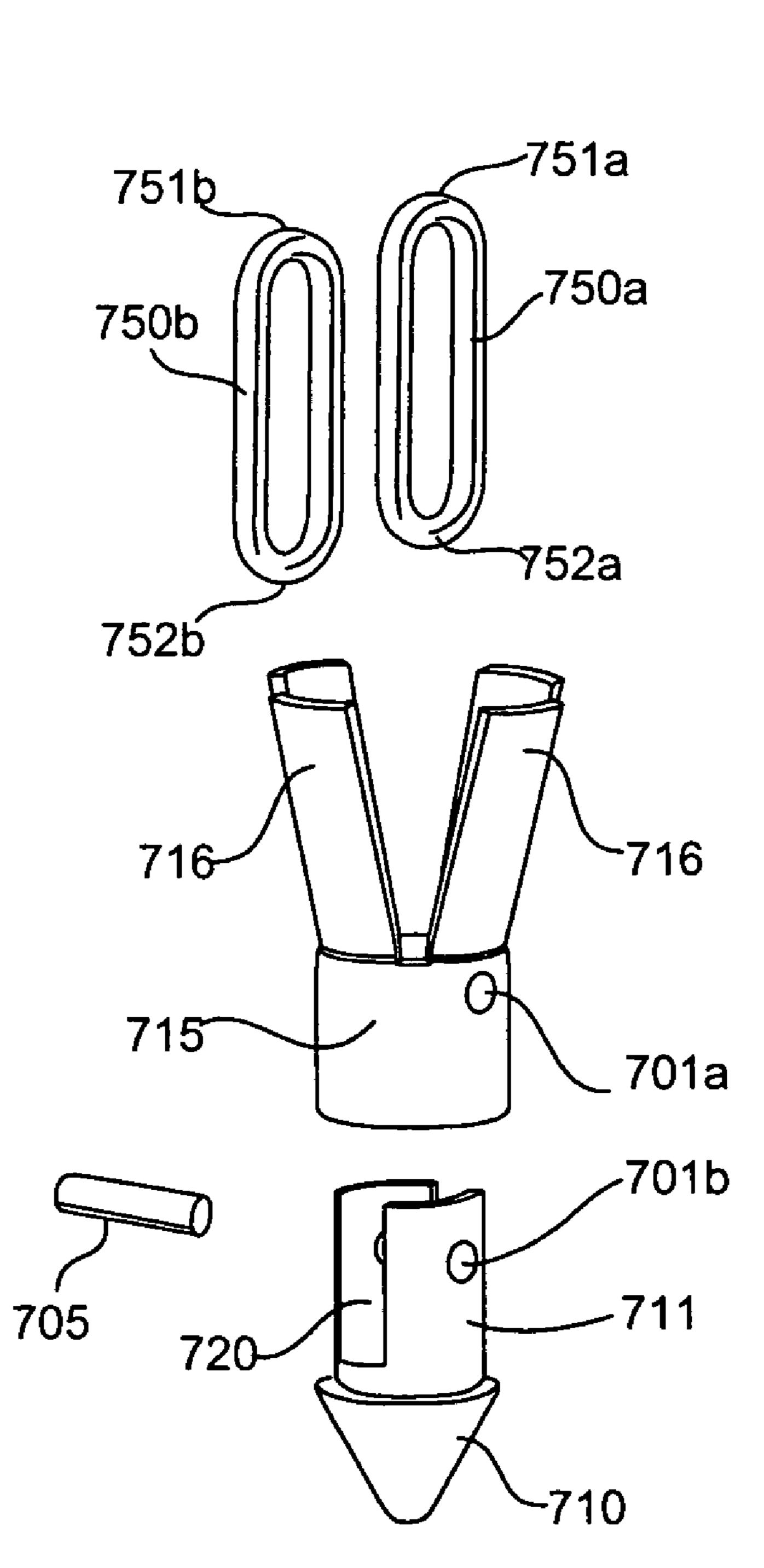


FIG. 30D

RING CINCH ASSEMBLY TO ATTACH BONE TO TISSUE

BACKGROUND

1. Field of the Invention

The present invention relates to systems, methods and apparatus for securing tissue to bone. More particularly, the invention relates to apparatus and methods for facilitating the attachment of tissue to bone using a bone anchoring system. 10

2. Description of the Related Art

Many attempts have been made to provide devices that allow the arthroscopic securing of torn tissue to a human bone. For example, numerous devices have been designed to allow a torn rotator cuff to be secured to a humeral head of the 15 shoulder.

Typically, in a first step, a hole is drilled into the bone under arthroscopic visualization. A length of a suture length is threaded through a portion of a tissue, and then coupled to a bone anchor configured. One or more sutures may be manipulated outside of the arthroscopic site.

Once the suture is coupled between the tissue and the bone anchor, the bone anchor may be inserted into the hole. The bone anchor may be configured to lock itself within the hole in the bone upon deployment therein. Several means for 25 securing the bone anchor within the hole of a bone are known in the art.

Once the bone anchor is secured within the hole in the bone, one or both ends of the suture may be tensioned to approximate the positioning of the tissue with respect to the 30 bone. Once the tissue is positioned as desired, the suture may be locked in place to maintain the tension in the suture. The free end or ends of the suture may be clipped under arthroscopic visualization to complete the procedure.

An example of a previously known method and apparatus 35 for attaching tissue to bone is described in U.S. Pat. No. 6,585,730 to Foerster, which is incorporated by reference herein. Foerster describes devices and methods for securing sutures to a bone anchor without the requirement of knot tying. In Foerster, suture legs, after having been placed into 40 soft tissues to be anchored to bone, are threaded through the anchor and then through a floating wedge block located at the distal end of the anchor. The wedge block is configured such that it has a hollow lumen through the center, and a conically tapered outer surface. The sutures are passed back around the 45 outside of the wedge block such that they rest on the conical surface. They are then re-threaded in the opposite direction back through the anchor, exiting the anchor at the proximal end thereof. The anchor is then inserted into the bone, and secured. When tension is placed on the legs of the suture 50 passing back out of the anchor, the suture is drawn through the hollow center lumen, around the distal end of the wedge block, and back out of the anchor. This tension tends to cause the wedge block to force its way back up into the anchor body, and a means to prevent this may be employed. Such means 55 may include any structure that selectively holds the wedge block separate from the anchor body.

At this juncture, by pulling on the suture legs, any slack in the sutures is removed, and the soft tissues are drawn toward the anchor. When the soft tissues are in the desired orientation, relative to the bone to which they are to be attached, the structure holding the wedge block is removed, and the back tension on the sutures pulls the wedge block into the matching taper in the anchor body, maintaining the compressive force on the suture legs.

Another previously known knotless suture anchor is described in U.S. Pat. No. 6,692,516 to West et al. ("West"),

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which is incorporated by reference herein. West describes a knotless suture anchor and method for knotlessly securing. The suture anchor has a deformable portion for engaging with a wall of a borehole in a first tissue member, a shaft for providing a force to the deformable portion to deform the deformable portion to cause the deformable portion to engage the wall of the borehole, a suture retaining portion in at least one of the deformable portion and the shaft for retaining two suture portions in the retaining portion with a loop formed between the two suture portions. The loop is adapted to traverse a second tissue member to be attached to the first tissue member. Application of the force to deform the deformable portion causes engagement of the deformable portion with the borehole to secure the suture anchor to the first tissue and clamping of at least one of the two suture portions in the suture retaining portion thereby to secure the suture forming the loop in the suture retaining portion and secure the second tissue to the suture anchor.

Systems, apparatus and methods are desired for securing tissue to bone that allow direct tactile feedback of the tension in the suture between the tissue and bone. During securing tissue to bone, it is desired to be able to adjust positioning of the tissue with respect to the bone. In securing the tissue to bone, the suture may be locked in place without tying a knot.

SUMMARY OF THE INVENTION

In some embodiments, a bone anchor system includes a main body and an insert. The bone anchor system is suitable for coupling a tissue structure to bone. The bone anchor system may insert in an opening of a bone. The insert includes a cavity disposed therein. The cavity has a proximal end, a distal end and an opening at the proximal end of the insert. The distal end of the cavity includes an inner surface.

In some embodiments, the bone anchor system includes a locking assembly. The locking assembly includes two or more locking elements configured be coupled to a suture, and to interact with each other to lock a suture in place to inhibit undesirable movement of the sutured tissue.

In some embodiments, the locking assembly is a two bar locking assembly. One or more of the locking elements may be axially moveable in the cavity. The locking elements are positioned with respect to each other to form a gap to allow a suture of a desired size. A suture positioned in the gap may be compressed and locked in place when tension in an undesirable direction is applied to the suture. In some embodiments, a suture may be threaded through a two bar locking assembly to permit movement of the suture only in a desired direction.

In some embodiments, a suture loop is coupled to a tissue and two ends of the suture are coupled to a two bar locking assembly. The suture ends pass though the opening of a first locking ring and then pass under and wrap around an upper bar of a second locking ring. The suture passes though a gap between the locking elements, under the upper bar of the first locking ring, and then around the upper bar of the first locking ring. Proximal ends of the suture are accessible. Optimization of tissue placement relative to a bone anchor may be achieved by individually tensioning each of the suture ends. Once in place, the suture is compressed between the locking elements, preventing the suture from slipping or moving in an undesirable direction. In some embodiments, the locking elements reversibly engage after the tissue has been placed. In some embodiments, apparatuses and methods for securing tissue to bone allow direct tactile feedback of the tension in the suture 65 between the tissue and the bone is obtained. In some embodiments, apparatuses and methods for securing tissue to bone allow tensioning both ends of a suture individually to enhance

placement of the tissue with respect to the bone. In some embodiments, apparatuses and methods for securing tissue to bone allow a suture to be locked in place without tying a knot.

In some embodiments, an apparatus is provided that includes a bone anchor member. The bone anchor member 5 may be securely disposed in a hole drilled in a bone. A suture length may be coupled between the bone anchor member and tissue. In some embodiments, a suture length is coupled between a plug portion that fits within a bore of the bone anchor member and the tissue. One or more ends of the suture 10 may be individually tensioned to enhance the placement of the tissue with respect to the bone and secure the suture.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the accompanying drawings in which:

- FIG. 1 is a schematic of a bone and tissue interface.
- FIG. 2A is a perspective front view of an embodiment of a 20 bone anchor.
- FIG. 2B is a perspective side view of the bone anchor along line A-A of FIG. 2A.
- FIG. 2C is a cross-sectional view of the bond anchor depicted in FIG. 2A.
 - FIG. 3A is a perspective side view of bone anchor.
 - FIG. 3B is exploded side view along line B-B of FIG. 3A.
- FIG. 3C is perspective top view of the bone anchor depicted in 3A.
- FIG. 3D is a perspective view of the top of the bond anchor 30 depicted in 3C in an open state.
- FIG. 3E is a cross-sectional view of the bone anchor depicted in FIG. 3A.
- FIG. 4A is a cross-sectional view of an embodiment of an apparatus that includes bone anchor member and a plug portion.
- FIG. 4B is a perspective side view of the plug portion depicted in FIG. 4A.
- FIG. 4C is a perspective side view of an opposing side of the plug portion depicted in FIG. 4A.
- FIG. **5**A is a cross-sectional view of an embodiment of a bone anchor that includes bone anchor member and a plug portion.
- FIG. **5**B is a perspective side view of the plug portion depicted in FIG. **5**A.
- FIG. 5C is a perspective side view of an opposing side of the plug portion depicted in FIG. 5A.
- FIG. 6A is a perspective side view of an embodiment of plug portion in a closed state.
- FIG. 6B is a perspective side view of the plug portion 50 in FIG. 23A. depicted in FIG. 6A in a partially open state.
- FIG. 6C is perspective a top view of the plug portion depicted in FIG. 6B.
- FIG. 7 is perspective side view of an embodiment of a plug portion in a partially open state.
- FIG. 8A is a perspective side view of an embodiment of a plug.
- FIG. 8B is a perspective side view of the plug depicted in FIG. 8A in a partially open state.
- FIG. 8C is a perspective top view plug depicted in FIG. 8A 60 in a fully open state.
- FIG. 9 is a cross-sectional view of an embodiment of a bond anchor having at least one adhesive delivery channel.
- FIG. 10A is a cross-sectional view of a bone anchor that includes a bone anchor member and a plug portion.
- FIG. 10B is a perspective view of the bone anchor of FIG. 10A positioned in a hole of a bone.

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- FIG. 11 is a cross-sectional view of an embodiment of a bone anchor that includes a bone anchor member and a plug portion.
- FIG. 12 is perspective side view of an embodiment of a bone anchor positioned in a bone with two openings.
- FIG. 13A is a cross-sectional view of an embodiment of a bone anchor that includes a bone anchor member and a plug portion.
- FIGS. 13B and 13C are illustrations of usage of the bone anchor depicted in FIG. 13A.
- FIG. 14 is a cross-sectional view of an embodiment of an apparatus that includes a bone anchor member with a spring element.
- FIG. 15A is perspective top view of top view of an embodiment of a bone anchor that includes a bone anchor and a plug portion.
- FIG. 15B is a cross-sectional view of the bone anchor depicted in FIG. 15A along line 15C-15C.
- FIG. 15C is perspective top view of the bone anchor of FIG. 15A in a locked state.
- FIG. 16 is a perspective view illustrating use of a suture in connection with the bone anchor depicted in FIGS. 15A-15C.
- FIGS. 17A and 17B are cross-sectional views of embodiments of a bone anchor in an unlocked state and a locked state, respectively.
 - FIGS. 18A and 18B are cross-sectional views of embodiments of a bone anchor in an unlocked state and a locked state, respectively.
 - FIGS. 19A and 19B are cross-sectional views of an alternative embodiment of the bone anchor depicted in FIGS. 17A and 17B.
 - FIGS. 20A and 20B are, respectively, a cross-sectional view and a perspective side view of an embodiment of an unlocked state of a bone anchor that includes a bone anchor member and a plug portion.
 - FIGS. 21A and 21B are, respectively, a cross-sectional view and a perspective side view depicted in FIGS. 20A and 20B in a locked state.
 - FIG. 22A is a cross-sectional view of an embodiment of a bone anchor that includes a bone anchor member and a plug portion.
 - FIG. 22B is a cross-sectional view of the plug portion inserted in the bone anchor member depicted in FIG. 22A.
 - FIG. 23A is a cross-sectional view of an embodiment of the plug depicted in FIGS. 22A and 22B.
 - FIG. 23B is a perspective side view of the plug depicted in FIG. 23A.
 - FIG. 23C is a perspective bottom view of the plug depicted in FIG. 23A.
 - FIG. **24**A is a cross-sectional view of an embodiment of a bone anchor that includes a bone anchor member and a plug portion.
- FIG. 24B is a cross-sectional view of a plug portion inserted into the bone anchor member depicted in FIG. 24A.
 - FIGS. 25A and 25B are illustrations of the bone anchor depicted in FIGS. 24A and 24B employing two sutures.
 - FIG. 26A depicts an embodiment of a bone anchor.
 - FIG. 26B is a cross-sectional view depicting a suture locking mechanism of the bone anchor depicted in FIG. 26A in a closed position.
 - FIG. **26**C is a cross-sectional view depicting the suture locking mechanism depicted in FIG. **26**B in an open position.
- FIG. **26**D is an exploded view of the bone anchor depicted in FIG. **26**A.
 - FIG. 27A is a perspective view of an embodiment of a bone anchor.

FIG. 27B is a cross-sectional view of the bone anchor depicted in FIG. 27A.

FIG. 27C is an exploded view of the bone anchor depicted in FIG. **27**A.

FIG. **28**A is a perspective view of an embodiment of a bone 5 anchor.

FIGS. **28**B and **28**C are cross-sectional views of the bone anchor depicted in FIG. 28A with release elements in the locked and unlocked positions, respectively.

FIG. 28D is an exploded view of the bone anchor depicted 10 in FIG. **28**A.

FIG. 29A depicts an embodiment of a bone anchor having a cam with a suture positioned between the cam and a surface at the distal end of the bone anchor.

FIG. **29**B is a cross-sectional view of the embodiment 15 depicted in FIG. 29A.

FIG. 29C is a perspective front view of the bone anchor depicted in FIG. 29A.

FIG. 29D is an exploded view of the bone anchor and suture depicted in FIG. 29A.

FIG. 30A depicts an embodiment of a bone anchor having a suture locking assembly.

FIG. 30B is a cross-sectional view of the bone anchor depicted in FIG. 30A.

FIG. 30C is a perspective side view of the bone anchor 25 depicted in FIG. 30A.

FIG. 30D is an exploded view of the bone anchor depicted in FIG. **30**A.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are 30 shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that the drawing and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION

FIG. 1 is an illustrative schematic of a bone and tissue interface. Tissue T has a torn end and it is desirable to secure the torn end to a section of bone B. In a first step, hole H having diameter d_H may be drilled in bone B, as depicted, using generally known bone drilling techniques.

Bone anchor member 20 may secure tissue T to bone B. Bone anchor member 20 may be used in conjunction with a length of suture 30. Suture 30 has first end 32a and second end 32b. Ends 32a, 32b may be coupled to bone anchor member 20. A central region of suture 30 forms loop 34. Loop 34 may 50 be threaded through a section of tissue T near the torn end of the tissue using generally known threading techniques. In embodiments described herein tissue, hole, and bone refer to T, H, and B, respectively, as described in FIG. 1.

FIG. 2A is a perspective front view of an embodiment of a 55 mately is situated in a manner depicted in FIG. 2C. bone anchor. FIG. 2B is a perspective side view of the bone anchor along line A-A shown in FIG. 2A. FIG. 2C is a crosssectional view of the bond anchor depicted in FIG. 2A. Bone anchor member 20 has proximal region 22 and distal region 24, as depicted in FIG. 2A. Bone anchor member 20 includes 60 a plurality of cleated members 42. Cleated members 42 may be formed on or attached to an exterior surface of bone anchor member 20. Cleated members 42 may secure bone anchor member 20 within a hole of a bone. In some embodiments, bone anchor member 20 may include radially expandable 65 members. Radially expandable members may embed into bone to secure the bone anchor member to the bone. In some

embodiments, bone anchor member 20 may include threaded exterior members. Threaded exterior members may screw into surrounding bone to secure the bone anchor member to the bone.

Referring to FIGS. 2B-2C, bone anchor member 20 includes first guide channel 50 and second guide channel 52. Guide channels 50, 52 are formed within opposing surfaces of bone anchor member 20. Guide channels 50, 52 are configured to accommodate regions of suture 30, so that the suture regions do not extend outside of the confines of the guide channels when in use.

Bone anchor member 20 includes first passage 60 and second passage 70. Passages 60, 70 extend laterally through a main body of bone anchor member 20, as depicted in FIG. 2C. Passage 60 communicates with first guide channel 50 via opening 61, and further communicates with guide channel 52 via opening 62. Similarly, passage 70 communicates with guide channel 50 via opening 71, and further communicates with guide channel 52 via opening 72.

Passage 60 is shown disposed proximal to second passage 70, i.e., the passage 60 is closer to proximal region 22 of bone anchor member 20. However, as will be apparent to one skilled in the art, the passages also may be disposed adjacent one another, or otherwise positioned, to achieve the objects of the present invention.

Passages 60, 70 include at least one cleated member 74. Cleated member 74 includes angled sections 75 and substantially orthogonal sections 76. Orthogonal sections 76 are disposed adjacent one another, thereby forming a cleated shape, as shown in FIG. 2C. Angled sections 75 are angled towards opening 62 of passage 60 and opening 72 of passage 70, as shown in FIG. 2C. In some embodiments, cleated passages 60, 70 are configured to permit one-way movement of first suture end 32a and second suture end 32b. For example, when suture end 32a is pulled in a proximal direction, angled sections 75 allow movement of the suture end in the proximal direction, while inhibiting distally advancement of suture end 32a within passage 60.

In certain embodiments, an outer diameter of suture 30 40 may be slightly larger than an inner diameter of cleated passages 60 and 70. Therefore, suture ends 32a and 32b can pass through cleated passages 60 and 70 in a proximal direction with relatively little resistance while the suture holds significantly greater force in the distal direction.

In one embodiment, a method for coupling suture 30 between tissue T and bone anchor member 20, a central region of suture 30 can be looped through tissue T first, such that free ends 32a and 32b extend from the tissue. Free end 32a is then threaded through one-way cleated passage 60 in a proximal direction, while free end 32b is threaded through one-way cleated passage 70, also in a proximal direction.

As will be apparent to one skilled in the art, suture 30 may be coupled between tissue T and bone anchor member 20 using other threading techniques, so long as the suture ulti-

First end 32a of suture 30 is disposed through first passage **60**, then transitioned into loop portion **34***a*. Loop portion **34***a* transitions into loop portion 34b, forming loop 34 therebetween, which is coupled to tissue T. Loop portion 34b transitions into second end 32b, which is disposed through passage 70, as shown in FIG. 2C. Accordingly, first and second ends 32a, 32b of suture 30 may be independently manipulated for purposes described herein below.

After suture 30 is coupled to bone anchor member 20 and a tissue, bone anchor member 20 is distally advanced into a hole of a bone under arthroscopic guidance. Exterior cleated members 42 of bone anchor member 20 allow the bone

anchor member to be advanced distally within the bone hole when an appropriate force is applied, but exterior cleated members 42 inhibit proximal movement of bone anchor member 20 to provide a secure anchor within the bone.

Pulling one or both of suture ends 32a and 32b proximally through cleated passages 60 and 70 may approximate the positioning of the tissue with respect to the bone. The use of two separate passages allows the surgeon to tension each end of the suture independently, which is often desirable when tissue is torn irregularly.

Further, the use of a plurality of cleated passages 60 70 permits incremental tensioning of first and second suture ends 32a, 32b. This allows incremental adjustment during positioning of the tissue, using tactile feedback as a guide. Once a desired tension is achieved, retraction of the suture ends is stopped, and the suture is automatically locked in place. Thus, there is no need to tie a knot.

In some embodiments, guide channels **50** and **52** permit the retraction of suture ends **32***a*, **32***b* when bone anchor member 20 **20** is secured within a hole of the bone by providing a clearance between the bone anchor member and the bone itself.

Alternatively, suture 30 may be coupled to bone anchor member 20 using techniques described herein below with respect to FIGS. 3A-3E or FIGS. 6-8. These techniques allow the suture to be coupled to bone anchor member 20 without the need to thread free ends 32a and 32b through passages 60 and 70.

FIGS. 3A-3E shows a further embodiment of bone anchor 20'. Bone anchor 20' includes a first mating portion 22a and a second mating portion 22b. In some embodiments, mating portions 22a, 22b are substantially symmetrical, except as noted below.

Turning to FIG. 3B, mating portion 22a includes cleated passage portion 60a and cleated passage portion 70a. Mating portion 22b includes cleated passage portion 60b and cleated passage portion 70b. When assembled state as shown in FIG. 3A, cleated passage portion 60a and cleated passage portion 60b form cleated passage 60', while cleated passage portions 40 70a and cleated passage portion 70b form cleated passage 70'.

Guide channel portions 50a of mating portion 22a and guide channel 50b of mating portion 22b form guide channel 50' in the assembled state as depicted in FIGS. 3A and 3C. Guide channel portion 52a of mating portion 22a and guide 45 channel portion 52b of mating portion 52b form guide channel 52' in the assembled state as depicted in FIG. 3D.

Mating portion 22a includes at least one mating pocket 59, as depicted in FIG. 3E. Mating portion 22b includes at least one protrusion 55, which is configured to securely engage a 50 corresponding pocket 59 in the assembled state of FIGS. 3A and 3C.

In a preferred embodiment, protrusion 55 includes ledge 57, as shown in detail "B" of FIG. 3D. Optionally, mating pocket 59 may include a complementary recess having a 55 slightly larger diameter (not shown), which is configured to receive ledge 57. In this manner, ledge 57 of protrusion 55 may snap into engagement with the larger diameter recess of pocket 59, thereby securing mating portions 22a, 22b.

During use, a first suture end may be positioned in cleated passage portion 60a, and a second suture end positioned in cleated passage portion 70a of FIG. 3E. Next, mating portion 22b is secured to mating portion 22a, (e.g., using a snap-lock engagement described above between protrusion 55 and pocket 59).

The first and second suture ends are disposed through cleated passages 60, 70. Using the bone anchor describe in

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FIGS. 3A-3E, threading the suture ends through cleated passages 60 and 70 is not necessary, thereby increasing the speed and ease of use of the device.

An alternate embodiment of bone anchor 100 is described in FIGS. 4A-4C. FIG. 4A is a cross-sectional view of an embodiment of a bone anchor that includes bone anchor member and a plug portion. FIG. 4B is a side view of the plug portion depicted in FIG. 4A. FIG. 4C is a side view of an opposing side of the plug portion depicted in FIG. 4A.

Referring to FIG. 4A, bone anchor 100 includes bone anchor member 102 and plug portion 110. Bone anchor member 102 includes main body 103 having bore 104 disposed therein. Main body 103 may include cleated members 106 disposed on the outer surface thereof. The shape and dimensions of cleated members 106 is not limited to that depicted in FIG. 4A. For example, cleated members 106 may be shaped substantially similar to the cleated members 42 of bone anchor member 20. Cleated members 106 are configured to insert into a hole of a bone using a frictional force fit.

During use, after bone anchor member 102 is secured in the hole, plug portion 110 may be inserted into bore 104 of bone anchor member 102. Plug portion 110 may include cleated members 116 on the outer surface thereof. Cleated members 116 may be configured to permit the advancement of plug portion into bore 104 and allow plug portion 110 to engage and frictionally grip inner wall 105, thereby securing the plug portion 100 to bone anchor member 102.

Referring to FIGS. 4B and 4C, plug portion 110 includes first and second passages 118 and 120. First and second suture ends 32a and 32b may be coupled to plug portion 110 of apparatus 100 in a manner similar to that described in FIG. 2C. First end 32a of suture 30 is disposed through first passage 118. After exiting through first passage 118, first end 32a then transitions into loop portion 34a, forms loop 34, and transitions into loop portion 34b (e.g., as shown in FIGS. 2A-2C). Loop portion 34b transitions into second end 32b, which extends through second passage 120.

Alternatively, suture 30 may be coupled to plug portion 110 using techniques described hereinbelow with respect to FIGS. 6-8. These techniques allow the suture to be coupled to plug portion 110 without the need to thread free ends 32a and 32b through passages 118 and 120, as set forth below.

If desired, passages 118 and 120 of FIGS. 4A-4C may include cleated members 74, as described hereinabove with respect to FIG. 2C. If cleated members 74 are employed, then tissue may be secured to a bone (e.g., see FIG. 1) by individually tensioning first and second ends 32a, 32b of suture 30, as described hereinabove.

Plug portion 110 preferably includes one or more guide channels 125 disposed in a lateral surface of plug body 113. Guide channel 125 preferably is substantially similar to guide channels 50 and 52 of FIG. 2C. In FIG. 4C, guide channel 125 is configured to permit retraction of first and second suture ends 32a and 32b when plug portion 110 is secured within bore 104 by providing a clearance between the plug portion and the bone anchor member.

Alternatively, passages 118 and 120 may be substantially smooth passages, such that cleated members 74 are not employed. In this case, passages 118 and 120 permit substantially unimpeded movement of suture 30 through the passages. In operation, suture ends 32a and 32b may be individually tensioned prior to insertion of plug portion 110 into bone anchor member 102. When the tissue has been appropriately secured to the bone, plug portion 110 is then forced into bore 104 of bone anchor member 102. This causes suture ends 32a and 32b to be sandwiched between plug portion 110 and bone

anchor member 102 when guide channels 125 are not present. Accordingly, the suture is secured between the two portions using a force fit.

FIGS. **5**A-**5**C show a further embodiment of a bone anchor apparatus. Bone anchor **140** may include bone anchor member **142** and plug portion a **150** as shown in FIG. **5**A. FIG. **5**B is a side view of the plug portion depicted in FIG. **5**A. FIG. **5**C is a side view of an opposing side of the plug portion depicted in FIG. **5**A.

Referring to FIG. 5A, apparatus 140 includes bone anchor member 142 and plug portion 150. Bone anchor member 142 includes main body 143 having bore 144 disposed therein. Main body 143 may include exterior cleated members 146 and interior cleated members 145 disposed on the inner surface of bore 144. Exterior cleated members 146 are configured to insert into a hole of a bone (e.g., see FIG. 1) using a force fit, as described in earlier embodiments above.

Plug portion 150 includes main body 153. In an embodiment, main body 153 may be substantially cylindrical in shape. In an embodiment, the exterior surface 156 of main 20 body 153 may be substantially smooth. Main body 153 may include taper 157 at the distal end thereof.

Suture 30 having first and second ends 32a, 32b is coupled to plug portion 150. A method of coupling is described hereinbelow with respect to FIGS. 6-8.

In operation, bone anchor member 142 is advanced into a hole of a bone (e.g., see FIG. 1). Exterior cleated members 146 of bone anchor member 142 permit one-way movement of the bone anchor member into the hole.

Plug portion 150 may be inserted into bore 144 of bone 30 anchor member 142. An outer diameter of exterior surface 156 of plug portion 150 may be slightly larger than an inner diameter of bore 144. Accordingly, when plug portion 150 is urged distally, a force fit is achieved to secure plug portion 150 within the bore of bone anchor member 142.

Taper 157 of plug portion 150 facilitates the distal advancement of the plug portion with respect to bone anchor member 142. Interior cleated members 145 are configured to permit advancement of plug portion 110 into bore 144 in a distal direction only.

First and second suture ends 32a and 32b may be coupled to plug portion 150 in a manner described hereinabove with respect to FIGS. 4A-4C. Specifically, first end 32a of suture 30 is disposed through first passage 158, and forms a loop that is threaded through a tissue. Second end 32b of suture 30 45 extends through second passage 160.

First and second passages 158, 160 may include cleated members 74 (see FIG. 2C). If cleated members 74 are employed, then tissue may be secured to the bone by individually tensioning first and second ends 32a, 32b of suture 50 30. Cleated members 74 permit incremental tensioning of each suture end, and serve to lock the suture ends within their respective passages 158 and 160, as generally set forth hereinabove with respect to FIG. 2C.

Plug portion **150** includes one or more guide channels **165** 55 disposed in a lateral surface of plug body **153**, as shown in FIG. **5**C. Guide channel **165** is configured to permit retraction of first and second suture ends **32***a*, **32***b* when plug portion **150** is secured within bore **144**. In some embodiments guide channel **165** is substantially similar to guide channel **50** of 60 FIG. **2**C.

Alternatively, passages 158, 160 may be smooth passages, such that cleated members 74 are not employed and guide channels 165 are not present. In some embodiments, passages 158, 160 may be substantially smooth. During use, suture 65 ends 32a, 32b may be individually tensioned prior to insertion of plug portion 150 into bone anchor member 142. When

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tissue is appropriately secured to the bone, then plug portion 150 is forced into bore 144 of bone anchor member 142. This causes suture ends 32a, 32b to be sandwiched between plug portion 150 and bone anchor member 142. Accordingly, the suture is secured between the two portions using a force fit.

Further embodiments of a plug portion are described in FIGS. 6A-6C. The plug portion may be used in bone anchors depicted in FIGS. 4A-4C. FIG. 6A is a side view of an embodiment of plug portion in a closed state. FIG. 6B is a side view of the plug portion depicted in FIG. 6A in a partially open state. FIG. 6C is a top view of the plug portion depicted in FIG. 6B.

Plug portion 110' includes first and second plug portions 110a, 110b, which are coupled together using hinge member 115. Hinge member 115 may be integral to first and second plug portions 110a, 110b, or the hinge member may be a third element that couples two distinct portions together.

Hinge member 115 permits plug portion 110' to transition between a closed state, as shown in FIG. 6A, and a partially or fully open state, as depicted in FIGS. 6B-6C, respectively. In the open states of FIGS. 6B-6C, a first suture end may be positioned (e.g., quickly positioned by a physician) in passage 118a and a second suture end positioned in passage 120a. Alternatively, the positioning of the suture ends may be reversed (e.g., first and second suture ends may be placed in passages 120b and 1118b, respectively).

With the suture ends in place, plug portion 110' may be transformed into a closed state, depicted in FIG. 6A, by rotating first and second plug portions 110a, 110b together. In the closed state, first and second plug portions 110a, 110b form first and second passages 118', 120'. With the sutures ends disposed in their respective passages, the apparatus may be actuated to secure tissue to bone.

As will be apparent to one skilled in the art, hinge member 115 serves to ensure proper alignment of first and second plug portions 110a, 110b in the closed state. If desired, a securing means, such as protrusion 55 and pocket 59 of FIGS. 3A-3E, may be employed to secure plug portions 110a and 110b. Further, as will be apparent to one skilled in the art, the securing means may be reversible, such that plug portions may be separated, as shown in FIGS. 6B-6C, to reposition the suture ends.

FIG. 7 depicts a perspective view of a plug in a partially opened state. Plug portion 110" includes first and second plug portions 110a', 110b', which have different sizes. Hinge member 115 is offset from the center of plug portion 110". Further, passage portions 118a' and 120a' of plug portion 110a' are each less than 180 degrees. By contrast, passage portions 118b' and 120b' of plug portion 110b' are each greater than 180 degrees.

During use, a first suture end may be positioned in passage portion 118b', and then a second suture end is placed in passage portion 120b'. Since these passage portions are each greater than 180, the suture ends may be pressed into the passage portions. Using such a method the suture ends remain at least partially in place. With the suture ends in place, plug portion 110" is transformed to a closed state. In the closed state, passage portions 118a', 118b' form a first one-way, 360-degree passage through which the first suture end may pass. The second passage portions 120a', 120b' form a second one-way, 360-degree passage through which the second suture end may pass.

Referring to FIGS. 8A-8C, yet another embodiment of a plug is described. FIG. 8A is a side view of an embodiment of a plug. FIG. 8B is a side view of the plug depicted in FIG. 8A in a partially open state. FIG. 8C is a top view plug depicted in FIG. 8A in a fully open state.

Hinge member 115 is located on a lateral surface of plug portion 110", as opposed to on the distal end of the plug portion, as shown in detail "D". Like the embodiment of FIGS. 6A-6C, the embodiment of FIGS. 8A-8C facilitates coupling of the suture to the plug portion. During use, threading of the suture through passages 118 and 120 of the plug portion is not required.

As will be apparent to one skilled in the art, passage portions 118a and 120a may be larger than passage portions 118b and 120b, respectively, as described with respect to FIG. 7 10 hereinabove.

Referring to FIG. 9, an embodiment of a bone anchor is described. Bone anchor member 180 is similar to bone anchor member 20 of FIGS. 2A-2C, except as noted hereinbelow. Cleated members **182** of bone anchor member **180** are similar 15 to cleated members 42 of bone anchor member 20, as described hereinabove, and facilitate anchoring of bone anchor member 180 within a hole of a bone. Further, guide channels 190 and 192 are similar to guide channels 50 and 52 of FIGS. **2A-2**C.

Unlike the embodiments described hereinabove, bone anchor member 180 includes at least one adhesive delivery channel 188, which is provided within main body 181. Adhesive delivery channel 188 may be formed by drilling a hole into an upper surface of main body 181, such that the hole 25 extends through first passage 184 and second passage 186. As will be apparent to one skilled in the art, however, channel 188 may be formed using other known techniques.

First and second passages **184** and **186** may include cleated members 74 of FIG. 2C, thereby permitting one-way movement of suture ends 32a and 32b through the passages. Alternatively, passages 184 and 186 may include substantially smooth inner surfaces that permit movement of suture 30 through the passages in either direction.

bone, the position of tissue relative to the bone may be approximated by individually tensioning first and second ends 32a, 32b of suture 30, as described extensively above an incorporated herein. When the tissue has the desired placement, an adhesive may be delivered to adhesive delivery 40 channel **188**. The delivery of an adhesive to channel **188** may be facilitated using a needle-like tube (not shown) disposed within a working cannula. The needle-like tube has a distal opening that may be placed in close proximity to, or within, adhesive delivery channel **188** to deliver an adhesive thereto. 45

The adhesive is allowed to flow distally through adhesive delivery channel 188 and into portions of first and second passages 184 and 186. The adhesive may contact at least a portion of suture 30 positioned in corresponding regions of first and second passages **184** and **186**, thereby locking the 50 suture in place. As will be apparent to one skilled in the art, although one adhesive delivery channel 188 is depicted in FIG. 9, multiple adhesive delivery channels may be employed to secure the suture, irrespective of whether cleated members 74 are employed.

Referring to FIG. 10A, apparatus 200 includes bone anchor member 202 and plug portion 210. Apparatus 200 is similar to apparatus 140 of FIGS. 5A-5C, except as noted below.

Bone anchor member 202 includes main body 203 having bore 204 disposed therein. Main body 203 of bone anchor 60 member 202 includes exterior cleated members 206, which are configured to be inserted into a hole of a bone (e.g., see FIG. 1) using a force fit, as described hereinabove.

Plug portion 210 may be substantially cylindrical in shape and includes main body 213. Main body 213 has smooth 65 exterior surface 216 and taper 217. Optionally, taper 217 may be formed at the distal end of main body 213.

Suture 30 having first and second ends 32a, 32b is coupled to plug portion 210, preferably in a manner described hereinabove with respect to FIGS. 6-8.

The outer diameter of main body 213 may be sized slightly larger than an inner diameter of bore 204. The size of diameter is selected to allow main body 213 of plug portion 210 to be distally advanced into bore 204 when forced. Taper 207 of bone anchor member 202 is facilitates advancement of plug portion 210 into bore 204.

In operation, bone anchor member 202 is secured within a hole of a bone when the bone anchor member is distally advanced into the hole, as depicted in FIG. 10B. Exterior cleated members 206 of bone anchor member 202 permit one-way movement of the bone anchor member into the hole.

Plug portion 210 is advanced distally into bore 204 of bone anchor member 202 and secured therein using a force fit, as described hereinabove. At this time, surrounding regions of the bone may apply a compressive force upon bone anchor member 202, as indicated by the larger directional arrows in 20 FIG. 10B. This compressive force upon bone anchor member 202 in turn causes compression upon plug portion 210, as indicated by the smaller directional arrows in FIG. 10B, thereby securely retaining the plug portion within bore 204.

In some embodiments, passages 218 and 219 may include cleated members 74 as described hereinabove with respect to FIG. 2C. Alternatively, passages 218 and 219 may include substantially smooth interior surfaces that permit advancement of suture 30 in either direction.

In certain embodiments, the position of the tissue relative to the bone may be approximated by individually tensioning suture ends 32a and 32b prior to insertion of plug portion 210 into bone anchor member 202. In some embodiments, the tissue position is approximated when passage 219 is disposed just above bore 204. Once the desired positioning of the tissue After bone anchor member 180 is secured in a hole the 35 is achieved, plug portion 210 is advanced distally into bore **204**, thereby locking the suture. Specifically, the suture will be sandwiched between exterior surface 216 of plug portion 210 and inner wall 205 of bone anchor member 202.

> Referring to FIG. 11, apparatus 220 may include a bone anchor member 222 and a plug portion 230. Apparatus 220 is similar to apparatus 200 of FIGS. 10A-10B, except as noted below.

> Bone anchor member 222 includes main body 223 having bore **224** disposed therein, as depicted in FIG. **11**. Further, main body 223 includes exterior cleated members 226, which are configured to be inserted into a hole of a bone (e.g., see FIG. 1) using a force fit, as described hereinabove. Bone anchor member 222 includes a proximal protrusion having inward taper 227. Proximal stop 228 is formed between inward taper 227 and inner wall 225 of bone anchor member **222**.

Plug portion 230 includes main body 233 having proximal region 235, central region 234 and tapered distal region 237. Tapered distal region 237 is sized to pass through taper 227 of 55 bone anchor member 222 when a distally directed force is applied to plug portion 230. When further force is applied, central region 234 of plug portion 230 is advanced into bore 224 via taper 227. When further force is applied to plug portion 230, proximal region 235 is advanced past taper 227. Once proximal region 235 is fully inserted into bore 224, proximal stop 228 is configured to abut proximal edge 236 of plug portion 230, thereby securing the plug portion within bone anchor member 222.

As will be apparent to one skilled in the art, apparatus 220 may further include any of the other features described above with respect to the embodiments of FIGS. 2-10. For example, passages 238 and 239 may include cleated members 74 of

FIG. 2C, or alternatively may include substantially smooth interior surfaces. Further, the operation of apparatus 220 preferably is substantially similar to the methods described hereinabove with respect to the embodiments of FIGS. 2-10.

In some embodiments, a bone anchor may be positioned in 5 bone throughole H_T , which has two openings to the surface of the bone. Referring to FIG. 12, bone anchor 240 is similar to bone anchor member 20 of FIGS. 1-2, but is configured for use in applications where through hole H_T is employed.

Bone anchor 240 includes main body 242 having proximal and distal ends. Flange 245 disposed at the proximal end and taper 246 formed at the distal end of main body 242. Main body 242 includes exterior surface 243 disposed between flange 245 and taper 246.

Bone anchor **240** includes first and second passages **250** 15 and **252**, each having a plurality of cleated members **254**. Each of the cleated members includes angled sections **255** and substantially orthogonal sections **256**, which are disposed adjacent one another thereby forming a cleated shape, as described hereinabove with respect to cleated members **74** 20 of FIG. **2**C.

During use, a loop of suture 30 may be coupled through tissue T first, with free ends 32a and 32b extending from the tissue. Free end 32a then is threaded through first passage 250 in a proximal direction. Free end 32b is threaded through 25 second passage 252, also in a proximal direction. The suture may be threaded through passages 250, 252 and tissue T by arthroscopically operating on one or both sides of bone B.

As will be apparent to one skilled in the art, suture 30 may be coupled between tissue T and bone anchor 240 using other arthroscopic threading techniques, so long as the suture ultimately is situated in a manner depicted in FIG. 12.

Once the suture is threaded as shown in FIG. 12, first and second suture ends 32a and 32b may be proximally retracted, one at a time, to approximate the position of tissue T with 35 respect to bone B. As the suture ends are tensioned, flange 245, which has an outer diameter larger than the diameter of through hole H_T , abuts bone B. The system becomes tensioned because flange 245 and tissue T are drawn against the bone from opposing directions.

In accordance with one aspect of the present invention, cleated passages 250 and 252 are configured to permit one-way movement of first and second suture ends 32a and 32b, respectively. For example, when first end 32a is pulled in a proximal direction, angled sections 255 permit movement of 45 the suture end in the proximal direction. However, suture end 32a is inhibited from distally advancing within passage 250. The use of two separate passages allows each end of the suture to be separately tensioned, which is often desirable when tissue T is torn irregularly.

As will be apparent to one skilled in the art, the methods described in FIG. 12 may be accomplished using a separate bone anchor member and plug portion. For example, the principles of the embodiments in FIGS. 4-5 and FIGS. 10-11, in which separate bone anchor and plug portions are 55 employed, may be implemented in lieu of one-piece bone anchor 240.

Further, the suture securing methods described in FIG. 12 may be accomplished using substantially smooth passages 250 and 252. Where substantially smooth passages are 60 employed, an interference fit or an adhesive may be employed in lieu of the cleated passages to facilitate securing of the suture. The interference fit or adhesive may be used, for example, as described hereinabove with respect to the embodiments of FIGS. 4-5 and FIGS. 10-11.

FIG. 13A is a cross-sectional view of an embodiment of an apparatus that includes a bone anchor member and a plug

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portion. As shown in FIG. 13A, apparatus 270 includes bone anchor member 272 and plug portion 280. Bone anchor member 272 includes main body 273 having bore 274 disposed therein. Main body 273 includes exterior cleated members 276, which are configured to be inserted into a hole of a bone (e.g., see FIG. 1) using a force fit, as described hereinabove. Bone anchor member 272 includes a proximal protrusion having inward taper 277. Proximal stop 278 is formed between inward taper 277 and an inner wall of bone anchor member 272.

Bone anchor member 272 includes first and second spring elements 292a and 292b, which are disposed at a distal region of bore 274. First and second spring members 292a and 292b may be integrally formed with bone anchor body 273, or may be separate elements coupled to body 273. First and second spring elements 292a and 292b may be deformed to accommodate plug portion 280 within bore 274, and also to enable locking and unlocking of a suture (not shown in FIGS. 13A-13C) used in conjunction with apparatus 270. As will be apparent to one skilled in the art, one or more spring elements may be employed.

First and second passages 298 and 299 extend laterally through main body 273 of bone anchor member 272. First and second passages 298 and 299 are configured to selectively align with first and second passages 288 and 289 of plug portion 280, for the purposes described hereinafter.

Plug portion 280 of apparatus 270 includes main body 283 having proximal and distal ends. The proximal end includes flange 284. Taper 286 is disposed between flange 284 and main body 283. Distal taper 287 is disposed at the distal end of plug portion 280.

Plug portion 280 includes first and second passages 288 and 289, which extend laterally through main body 283. In some embodiments, first and second passages 288 and 289 include substantially smooth interior surfaces.

FIG. 13B illustrates use of apparatus 270. First, plug portion 280 is inserted into bore 274 of bone anchor member 272, using insertion tool 294. When an appropriate force is applied to plug portion 280, tapered distal end 287 passes through taper 277 of bone anchor member 272. When further force is applied, a central region of plug portion 280 is advanced into bore 274 via taper 277. When further force is applied to plug portion 280, the proximal region having taper 286 and flange 284 is then advanced past taper 277.

When plug portion 280 is fully inserted into bore 274, first and second spring elements 292a and 292b are inclined to urge plug portion 280 in a proximal direction, to allow flange 284 to abut proximal stop 278 (see FIG. 13C). However, when a sufficient distally directed force is applied to plug portion 280, (e.g., using insertion tool 294) first and second spring elements may be deformed distally (see FIG. 13B).

Insertion tool **294** may be a rod or other substantially rigid member configured to transfer a distally directed force from a physician to plug portion **290**. In some embodiments, insertion tool **294** is engages mating slot **295**, as shown in FIG. **13**B.

The provision of distally directed force acting on plug portion 280 causes first and second passages 288 and 289 to become substantially aligned with first and second passages 298 and 299 of bone anchor member 27, respectively, as shown in FIG. 13B. At this time, a suture may be threaded through aligned first passages 288 and 298. The suture may be threaded through a tissue, as described hereinabove, and then threaded back through aligned second passages 289 and 299. First suture end 32a extends through first passages 288 and 298, while second suture end 32b extends through second passages 289 and 299.

Once the suture is coupled to apparatus 270, apparatus 270 is inserted into a hole of a bone under arthroscopic guidance. Cleated members 276 secure apparatus 270 within the hole, as described hereinabove. At this time, first and second suture ends 32a and 32b will extend outside of the arthroscopic field of vision.

First and second suture ends 32a and 32b may be selectively tensioned to approximate the positioning of the tissue with respect to the bone when first and second passages 288 and 289 are aligned with first and second passages 298 and 10 299, respectively. During tensioning of the suture ends, insertion tool 294 urges plug portion distally to cause the passages to align, as shown in FIG. 13B.

When a desired positioning of the tissue is achieved, the force applied to plug portion 280 is removed (e.g., by proxinally retracting insertion tool 294, as shown in FIG. 13C). At this time, first and second spring elements 292a and 292b are inclined to bias proximally, thereby urging flange 284 of plug portion 280 against proximal stop 278 of bone anchor member 272. This movement of plug portion 280 with respect to bone anchor member 272 causes a misalignment between first passage 288 of plug portion 280 and first passage 298 of bone anchor member 272. Also, a misalignment occurs between second passages 289 and 299. Accordingly, the misalignments cause first suture end 32a to become pinched 25 between first passages 288 and 298, while second suture end 32b is pinched between second passages 289 and 299. These misalignments lock the suture in place.

If it becomes necessary to adjust the positioning of the tissue with respect to a bone during use, then insertion tool 30 **294** may be inserted into mating slot **295**, as shown in FIG. **13**B, to urge plug portion **280** distally. As described hereinabove, when first and second passages of plug portion **280** and bone anchor member **272** are aligned (see FIG. **13**B), suture ends **32***a* and **32***b* may be manipulated to adjust the position-35 ing of the tissue.

FIG. 14 is a perspective cross-sectional view of an embodiment of an apparatus that includes a bone anchor member and a plug portion. The apparatus is similar to the apparatus described in FIG. 13, except as described. Bone anchor member 272' includes spring element 292' disposed at a distal end of main body 273. Spring element 292' includes a distally concave configuration having a central region 293.

Bone anchor member 272' is used in conjunction with plug portion 280 in a manner similar to that described hereinabove 45 with respect to FIGS. 13A-13C. Specifically, after plug portion 280 is inserted into bore 274, the provision of a further distally-directed force acting on plug portion 280 causes central region 293 of spring element 292' to be deformed in a distal direction. When the central region of spring element 50 292' is deformed distally, first and second passages 288 and 289 of plug portion 280 are substantially aligned with first and second passages 298 and 299 of bone anchor member 272', respectively. In this state, first suture end 32a may move substantially unimpeded through aligned first passages 288 and 298, while second suture end 32b may move through aligned second passages 289 and 299, respectively, as described hereinabove with respect to FIG. 13B.

When a desired positioning of tissue is achieved, the force imposed upon plug portion **280** is removed (e.g., by proximally retracting insertion tool **294**, as described in FIG. **13**C) and central region **293** of spring elements **292**' returns in a proximal direction to its preferred orientation. This causes flange **284** of plug portion **280** to be urged against proximal stop **278** of bone anchor member **272**'. As described hereinabove, the movement of plug portion **280** with respect to bone anchor member **272**' causes a misalignment between first

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passages 288 and 298, and also a misalignment between second passages 289 and 299. These misalignments pinch suture ends 32a and 32b to lock the suture in place.

Referring to FIG. 15, an embodiment of an apparatus that includes a bone anchor member and a plug portion is described. FIG. 15A is top view of top view of an embodiment of an apparatus that includes a bone anchor and a plug portion. FIG. 15B is a cross-sectional view of the bone anchor depicted in FIG. 15A along line 15C-15C. FIG. 15C is top view of the bone anchor depicted in FIG. 15A in a locked state.

Apparatus 300 includes bone anchor member 302 and plug portion 310. Bone anchor member 302 is similar to the bone anchor members described hereinabove and includes main body 303 having plurality of cleated members 306, which are configured to anchor plug portion 302 within a hole of a bone (e.g., see FIG. 1). Bone anchor member 302 includes central bore 304, which is configured to receive plug portion 310.

Plug portion 310 of apparatus 300 includes main body 311 having distal region 318 and central bore 312, as shown in FIG. 15B. Main body 311 has an outer diameter that is slightly smaller than an inner diameter of bore 304. Accordingly, plug portion 310 is configured for circumferential rotation within bore 304 of bone anchor member 302.

Bone anchor member 302 includes first and second semicircular channels 305a and 305b, which are formed at diametrically opposing surfaces of main body 303, as shown in FIGS. 15A and 15B. Further, plug portion 310 includes first and second semi-circular channels 315a and 315b, which are formed at diametrically opposing surfaces on main body 311, as shown in FIGS. 15A and 15B.

Apparatus 300 also includes actuation knob 321, which is disposed on an outer surface of plug portion 310, as shown in FIG. 15A. Actuation knob 321 is configured to be disposed within first recess 322 of bone anchor member 302 in an unlocked state, and disposed within second recess 323 in a locked state.

When actuation knob 321 is disposed within first recess 322, first and second semi-circular channels 305a and 305b of bone anchor member 302 are aligned with first and second semi-circular channels 315a and 315b of plug portion 310, respectively, thereby forming first and second circular channels, as shown in FIGS. 15A and 15B.

When actuation knob 321 is disposed within second recess 323, first and second semi-circular channels 305a and 305b of bone anchor member 302 are not aligned with corresponding channels 315a and 315b of plug portion 310, as shown in FIG. 15C.

During use, suture 30 is coupled to apparatus 300 in a manner shown in FIG. 16. Specifically, first suture end 32a extends through central bore 312 of plug portion 310. First suture end 32a passes through aperture 327 in plug portion 310 (see FIG. 15B) and transitions into loop portion 34a. Loop portion 34a is threaded through the first circular channel formed by semi-circular channels 305a and 315a.

Loop portion 34a then is threaded through a tissue and transitions into loop portion 34b. Loop portion 34b is threaded through the second circular channel formed by semi-circular channels 305b and 315b. Loop portion 34b passes through a second aperture 327 and transitions into second suture end 32b. Second suture end 32b extends through central bore 312 of plug portion 310.

During use, first and second suture ends 32a and 32b may be selectively tensioned when actuation knob 322 is disposed within first recess 322, as shown in FIGS. 15A-15B. This is because first and second semi-circular channels 305a and 305b of bone anchor member 302 are aligned with first and

second semi-circular channels 315a and 315b of plug portion 310, respectively, to form the first and second circular channels through which the suture can freely pass.

It should be noted that, as first and second ends 32a and 32b are individually tensioned, rounded edges 328 of plug portion 5 310 (see FIG. 15B) serve to reduce the shear stresses imposed upon the suture ends as they pass through apertures 327.

To lock the suture in place, plug portion 310 is rotated with respect to bone anchor member 302 to cause actuation knob 321 to be advanced into second recess 323. The rotation of 10 plug portion 310 may be achieved by inserting an actuation tool such as a hexagonal key (not shown) into mating slot 325. Once knob 321 is secured within second recess 323, as shown in FIG. 15C, the suture will be locked in place because the misaligned semi-circular channels pinch the first and second 15 ends of the suture.

The positioning of tissue may be optimized (e.g., tweaked) with respect to bone after the suture has been locked, the actuation tool may be inserted into mating slot 325 and force applied to cause knob 322 to rotate in an opposing direction 20 into first recess 322. As described above, this forms two fully circular channels through which the suture may be advanced or retracted to facilitate positioning of the tissue with respect to the bone.

FIGS. 17A and 17B depict cross-sectional views of 25 embodiments of a bone anchor in unlocked and locked states, respectively. Referring to FIG. 17A, bone anchor member 340 includes main body 343 having proximal and distal regions. Bone anchor member 340 includes a plurality of cleated members 346, and opposing guide channels 348 and 30 349. In some embodiments, guide channels 348 and 349 are similar to guide channels 50 and 52 of FIG. 2C.

Bone anchor member 340 includes at least one passage 352 and flexible member 350. Passage 352 extends laterally through main body 343. Flexible member 350 is disposed 35 proximal to passage 352. Flexible member 350 has a relaxed configuration in which it assumes a convex shape (e.g., bowed away from passage 352). In the relaxed configuration, shown in FIG. 17A, there is sufficient clearance between flexible member 350 and passage 352 to permit suture 30 to move 40 substantially unimpeded through the passage.

In use, before bone anchor member 340 is inserted into a hole of a bone, first suture end 32a is passed through passage 352. The first suture end then becomes loop portion 34a, which is threaded through the tissue, as described herein-45 above. Loop portion 34a extends through the tissue to become loop portion 34b. Loop portion 34b passes back through passage 352 and becomes second suture end 32b. First and second suture ends 32a and 32b extend outside of the arthroscopic site and may be individually tensioned during use.

After suture 30 is coupled to apparatus 340 and the tissue, bone anchor member 340 is advanced distally into a hole of a bone (e.g., see FIG. 1), whereby cleated members 346 serve to anchor the device in the hole. As described above, first and second suture ends 32a and 32b may be individually tensioned to approximate the positioning of the tissue with respect to the bone. During this time, no external forces are applied to flexible member 350, thereby permitting movement of the suture within passage 352.

Once a desired tissue positioning is achieved, the suture 60 may be locked in place by apply a distally directed force upon flexible member 350, as depicted in FIG. 17B. Flexible member 350 preferably assumes a concave shape in which distal knob 354 is urged towards corresponding pocket 355 in bone anchor member 342. The distally directed force locks the 65 suture in place by pinching the suture and inhibiting its movement within passage 352.

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As will be apparent to one skilled in the art, any number of mechanisms may be employed to apply a distally directed force upon flexible member 350, and further, to lock the flexible member in the concave position depicted in FIG. 17B. For example, a plug may be inserted into bore 358, and then wedged against flexible member 350 to hold the flexible member in place. Alternatively, bone anchor member 340 may include taper 277 and proximal stop 278 (see FIG. 17A) to allow the plug to remain in place within bore 358. In either case, the plug serves to apply a compressive force to hold the suture in the locked state.

Alternatively, the flexible member may be "bi-stable," such that the flexible member has only two stable states. In the first state, the flexible member is positioned as shown in FIG. 17A. When a sufficient distally directed force is applied, the flexible member is configured to "snap" from the first state into a second state, as shown in FIG. 17B. There are no stable positions between the first and second state. Accordingly, the flexible member is either provided in a locked or unlocked state. Means for applying a proximally-directed force to the flexible member may be used to cause the flexible member to snap from the second state, shown in FIG. 17B, to the first state, shown in FIG. 17A, thereby unlocking the device.

In some embodiments, a threaded member may be used to hold the suture in a locked state. As shown in FIGS. 18A-18B, threaded cap 360 has exterior thread 361, which is adapted to engage grooved interior section 371 of bore 358'. In certain embodiments, threaded cap 360 includes a proximal region having mating slot 365 and a distal region having distal protrusion 362.

In an unlocked state, threaded cap 360 is situated proximally within bore 358', as shown in FIG. 18A. To lock the suture in place, locking tool 375 may be inserted into mating slot 365 and then rotated clockwise to advance threaded cap in a distal direction (e.g., in a manner similar to tightening a screw). This causes a distal region of threaded cap 360, and distal protrusion 362, to urge flexible member 350 distally, thereby impinging upon a suture length disposed through passage 352. This locks the suture in place.

If re-adjustment of the suture, then locking tool 375 may be rotated counterclockwise within mating slot 365 to proximally retract the threaded cap. This will remove the forces imposed upon the suture, as depicted in FIG. 18A.

In some embodiments, flexible member 350 is omitted entirely. In this case, threaded cap 360 may directly pinch the suture in passage 352 to lock the suture in place.

Referring now to FIGS. 19A-19B, an alternative embodiment of the bone anchor of FIGS. 17A-17B is described. Operation of bone anchor member 340" is substantially the same as that of bone anchor 340, with the main exception that locking member 380 is provided in lieu of flexible member 350.

Locking member 380 includes cylindrical body 381, which is configured to be confined within recess 391 of main body 343", as shown in FIG. 19A. Locking member 380 includes distal protrusion 382, which is configured to extend at least partially through aperture 390 of main body 343".

First and second support members 383a and 383b are disposed beneath cylindrical body 381, and may be formed integrally with locking member 380. As shown in FIG. 19A, the first and second support members 383a and 383b rest on support ledge 395 of main body 343", thereby elevating locking member 380 within recess 391.

During use, suture 30 is secured to a tissue and disposed through passage 352", as described hereinabove with respect to FIGS. 17A-17B. Bone anchor member 340" then is

advanced distally into a hole of a bone (e.g., see FIG. 1), such that cleated members **346** anchor the device in the hole.

When locking member 380 is elevated within recess 391, distal protrusion 382 may not substantially extend into passage 352", thereby permitting movement of the suture within passage 352". At this time, first and second suture ends 32a and 32b may be individually tensioned to approximate the positioning of the tissue with respect to the bone.

Once a desired positioning is achieved, the suture may be locked in place by any number of techniques that cause first and second support members 383a and 383b to be lowered or eliminated, thereby lowering cylindrical body 381 within recess 391 and urging distal protrusion 382 towards corresponding pocket 355", as depicted in FIG. 19B. The distally directed force applied by distal protrusion 382 secures the suture in place.

In certain embodiments, first and second support members 383a and 383b may be fused with support ledge 395 of main body 343". In some embodiments, ultrasonic energy is delivered to a proximal surface of locking member 380, via bore 358", using techniques that are known in the art. The provision of ultrasonic energy causes first and second support members 383a and 383b to fuse with support ledge 395, thereby lowering locking device 380 and locking the suture 25 disposed within passage 352" in place.

In the embodiments of FIGS. 17-19, while only one passage 352 is depicted, it will be apparent to one skilled in the art that a second passage may be provided, (e.g., disposed adjacent to the first passage). If two adjacent passages 352 are 30 provided, then the suture can be threaded through the first passage, through the tissue, and threaded back through the second passage.

Further, it will be apparent to one skilled in the art that an adhesive, for example, cyanoacrylate, epoxy, bone cement 35 and so forth, may be employed in conjunction with any of the embodiments described in FIGS. 17-19. Such an adhesive may be used in conjunction with apparatus including, but not limited to, flexible member 350, threaded cap 360, locking member 380, and any associated components.

FIGS. 20A and 20B are, respectively, a top-sectional view and a side view of embodiments of a locked state of an apparatus that includes a bone anchor and a plug portion. FIGS. 21A and 21B are, respectively, a top-sectional view and a side view depicted in FIGS. 20A-20B in a locked state. 45 Apparatus 400 (see FIG. 20A) includes bone anchor member 402 and plug portion 410.

Bone anchor member 402 includes main body 403 having cleated members 406, which are configured to secure bone anchor member 402 in a hole of a bone, as described herein-50 above. Bone anchor member 402 also includes first and second passages 408 and 412, which extend laterally through main body 403.

Bone anchor member 402 further includes guide channels 409a, 409b, 413a and 413b, which are disposed in exterior 55 surfaces of main body 403. The guide channels preferably are similar to guide channels 50 and 52 of FIGS. 2A-2C, except that four guide channels are employed in the present embodiment.

In use, first suture end 32a passes through guide channel 60 409a, through passage 408 and through guide channel 409b. The first suture end then transitions into loop 34, which is threaded through a tissue. Loop 34 of suture 30 then transitions into second suture end 32b. Second suture end 32b passes through guide channel 413b, through passage 412, and 65 through guide channel 413a. Accordingly, the suture is coupled between the tissue and apparatus 400.

Plug portion 410 having main body 411 is configured to be disposed within a central bore of bone anchor member 402. Plug portion 410 includes actuation knob 422, which is configured to be disposed in first recess 423 of bone anchor member 402 in an unlocked state, and disposed within second recess 424 in a locked state.

In the unlocked state, (e.g., when knob 422 is disposed within first recess 423) plug portion 410 is oriented such that main body 411 does not substantially overlap with first and second passages 408 and 412 of bone anchor member 410.

In some embodiments, first and second ends 32a and 32b of suture 30 are selectively tensioned when knob 422 is disposed within first recess 423. This is because first and second passages 408 and 412 provide a substantially unimpeded circular channel within which the suture can pass.

To lock the suture in place, plug portion 410 is rotated to cause knob 422 to be advanced into second recess 424. The rotation of plug portion 410 with respect to bone anchor member 402 may be achieved by inserting an actuation tool (e.g., a rectangular key) into mating slot 427. Once knob 422 is secured within second recess 424, the suture is locked in place because main body 411 of plug portion 410 impinges upon passages 408 and 412.

To adjust (e.g., tweak) the positioning of the tissue with respect to the bone after the suture is in the locked state, the actuation tool may be inserted into mating slot 427 to cause knob 422 to rotate back into first recess 423 (see FIGS. 20A-20B). This removes the compressive forces imposed upon the suture, to allow the first and second ends of the suture to be individually tensioned, thus facilitating re-positioning of the tissue.

FIGS. 22A and 22B are cross-sectional views of an embodiment of an apparatus that includes a bone anchor member and a plug portion.

Referring to FIG. 22A apparatus 440 includes bone anchor member 442 and plug portion 450. Bone anchor member 442 includes main body 443 having cleated members 446, which are configured to secure bone anchor member 442 in a hole of a bone (e.g., see FIG. 1). Further, bone anchor member 442 includes central bore 444 and circumferential protrusion 449, which is disposed near a distal end of bore 444.

Plug portion 450 has main body 451 having proximal and distal regions. The proximal region includes first and second guide channels 456 and 457, which are recessed in opposing lateral surfaces of main body 451. The distal region of main body 451 includes circumferential recess 453 and distal taper 454. Plug portion 410 also has a central region having passage 448 disposed laterally therethrough.

Before plug portion 450 is inserted into bore 444, first suture end 32a is passed through passage 448. The first suture end then becomes loop portion 34a, which is threaded through a tissue. Loop portion 34a extends through the tissue to become loop portion 34b. Loop portion 34b passes back through passage 448 and becomes second suture end 32b. First and second suture ends 32a and 32b may be manipulated during use.

Alternatively, as described hereinabove, a central region of suture 30 may be threaded through the tissue, and the free ends of the suture then may be passed through passage 448 in a proximal direction to achieve the depicted position of the suture.

In some embodiments, bone anchor member 442 is inserted into a hole of the bone before plug portion 450 is inserted into bore 444. Once bone anchor member 442 is securely disposed within the hole, plug portion 450 is positioned slightly above bone anchor member 442, so that passage 448 is proximal to bore 444. At this time, first and second

suture ends 32a and 32b may be individually tensioned to approximate the positioning of the tissue with respect to the bone (e.g., see FIG. 1).

Once the desired positioning is achieved, plug portion 450 may be advanced distally into bore 444 of bone anchor member 442. An insertion tool, such as insertion tool 294 of FIGS. 13A-13C, may be inserted into mating slot 458 to advance plug portion 450 distally. The provision of a sufficient distally directed force urges taper 454 over circumferential protrusion 449, thereby locking the plug portion within the bone anchor member, as shown in FIG. 22B.

At this time, first and second suture ends 32a and 32b are compressed within guide channel 456, while suture loop portions 34a and 34b are compressed within guide channel 457. Guide channels 456 and 457 may be sized to ensure that the suture is completely locked in place when plug portion 450 is inserted into bore 444 (see FIG. 22A). Alternatively, guide channels 456 and 457 may be sized to permit incremental adjustments of the suture, such that applying a sufficient tension to free ends 32a and 32b will overcome the frictional 20 forces between the suture, plug portion 450 and bone anchor member 442.

Referring to FIGS. 23A-23C, an embodiment of the 450 of FIGS. 22A-22B is described. FIG. 23A is a cross-sectional view of an embodiment of the plug depicted in FIGS. 22A and 25 22B. FIG. 23B is a perspective side view of the plug depicted in FIG. 23A. FIG. 23C is a bottom view of the plug depicted in FIG. 23A.

In FIG. 23A, plug portion 450' includes distal passage 466, in lieu of passage 448 of FIGS. 22A-22B. Distal passage 466 30 is formed as a slot recessed in the distal end of main body 451. Distal passage 466 may communicate with opposing guide channels 456 and 457.

The operation of a bone anchor system using plug portion 450' is substantially similar to the steps described in FIGS. 35 22A-22B, with the exception that first and second suture ends 32a and 32b are disposed within distal passage 466. Specifically, during use, suture ends 32a, 32b can be looped around the distal end of plug portion 450', and need not be inserted by threading through central passage 448. Once the suture ends are looped around the distal end of plug portion 450' and confined within passage 466, then the suture may be held in place while inserting plug portion 450' into bone anchor member 442. Once the plug portion is locked into place via circumferential protrusion 449 (e.g., as described in FIG. 45 22B), then the suture is compressed between plug portion 450' and bone anchor member 442.

Referring to FIG. 24A, an apparatus includes alternative bone anchor member 442" and alternative plug portion 450". Bone anchor member 442" and alternative plug portion 450" are similar to bone anchor member 442 and plug portion 450 of FIGS. 22A-22B, except as noted below.

Plug portion 450" includes main body 451' having first suture clearance channel 456' formed in a first lateral surface of the body, and second suture clearance channel 457' formed 55 in an opposing lateral surface of the body. Plug portion 450" also includes clearance recess 455 on a distal region of main body 451', along with suture channel 466'.

Main body 451' includes a plurality of cleated members 459a, which are formed adjacent to suture channel 466'. Also, 60 bone anchor portion 442" includes a plurality of cleated members 459b formed in bore 444. Cleated members 459b are configured to oppose cleated members 459a when plug portion 450" is disposed in bore 444 of bone anchor member 442", as shown in FIG. 24B.

During use, suture length 30a is coupled to bone anchor member 442" by first forming loop 470 between regions 35a

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and 35b of the suture. A central portion of suture 30a then is looped around suture channel 466' of plug portion 450". At this time, proximal suture ends 33a and 33b are proximate clearance channel 456', while suture regions 35a and 35b are in the vicinity of clearance channel 457'. Plug portion 450" then is lowered into bore 444 of bone anchor member 442", as depicted in FIG. 24B.

When an appropriate force is applied, distal taper 454 of plug portion 450" passes over protrusion 449 of bone anchor member 442". At this time, protrusion 449 is confined within recess 453, as shown in FIG. 24B, to substantially inhibit movement of plug portion 450" with respect to bone anchor member 442". Proximal suture ends 33a and 33b are disposed within clearance channel 456', while suture regions 35a and 35b are disposed within clearance channel 457'.

In certain embodiments, suture loop 470 may be coupled directly to a tissue, as generally set forth hereinabove. Tensioning of suture ends 33a and 33b may directly effect positioning of the tissue. Further, as set forth above, cleated members 459a and 459b may form a one-way channel that facilitates tensioning of the suture ends, and locks the suture ends in place. In some embodiments, a second suture length may be employed to anchor a tissue to a bone. FIGS. 25A-25B are illustrations of the bone anchor depicted in FIGS. 24A and 24B employing two sutures.

In FIG. 25A, second suture length 30b has loop 471, which is coupled directly to tissue T. Loop 471 is formed between suture portions 34a and 34b. Proximal to suture portions 34a and 34b, second suture 30b includes proximal ends 32a and 32b, which are configured to be manipulated during use.

Second suture 30b is coupled to first suture 30a by pulling proximal ends 32a and 32b through loop 470. At this time, four proximal suture ends will extend proximally from an access cannula (not shown). Specifically, proximal ends 32a and 32b of second suture 30b, along with proximal ends 33a and 33b of first suture 30a, all extend from the access cannula. Each of the four suture ends may be individually tensioned during use.

As each of the four suture ends 32a, 32b, 33a and 33b are selectively tensioned, loop 470 and suture regions 35a and 35b are urged towards clearance channel 457', as shown in FIG. 25B. When loop 470 is drawn towards clearance channel 457', second suture 30b also is drawn towards the clearance channel (i.e., because proximal ends 32a and 32b of the second suture have been previously pulled through loop 470).

At this time, the various suture regions that are drawn towards clearance channel 457' become inserted within the clearance channel to effectively lock the sutures in place. In effect, as tension is applied to the four suture ends 32a, 32b, 33a and 33b, tissue T is approximated to bone, and ultimately, the sutures are locked in place.

The use of the described method may save considerable time and effort during a surgical procedure. For example, bone anchor member 442", plug portion 450" and first suture 30a (including loop 470) may be provided in an already assembled state, as shown in FIG. 24B. These components need not be assembled during the surgical procedure.

At an appropriate time, second suture 30b is coupled to tissue T via loop 471. Using this method, it is not necessary to thread proximal suture ends 32a and 32b through plug portion 450" or bone anchor member 442" after suture 30b is coupled to tissue T. Rather, suture ends 32a and 32b are pulled through loop 470 of first suture 30a. In short, first suture 30a is coupled to tissue T, and then proximal ends 32a and 32b are guided through previously provided loop 470, thereby saving operating time and effort.

Referring to FIGS. 26A-26D, an apparatus that includes a bone anchor is described. FIG. 26A depicts an embodiment of bone anchor 500. FIG. 26B is a cross-sectional view depicting a suture locking mechanism of the bone anchor depicted in FIG. **26**B in a locked position. FIG. **26**C is a cross-sectional view depicting the suture locking mechanism depicted in FIG. 26B in an unlocked position. FIG. 26D is an exploded view of the bone anchor of depicted in FIG. 26A.

Bone anchor 500 includes main body 502 and insert 504. Main body 502 has cleats 506, which are used to secure the 10 bone anchor 500 to bone as discussed above. Main body 502 may have any other suitable feature to secure the anchor 500 to bone, such as an expandable portion, without departing from the scope of the invention.

Insert 504 is positioned in recess 508 in main body 502. 15 The suture enters apparatus 500 through the proximal end of recess 508 and extends through a space between main body **502** and insert **504**. The suture then passes hole **510** in insert **504**. Hole **510** is, in some embodiments, triangular shaped to accommodate different size suture as shown in FIG. 26D.

Insert **504** is movable between the closed position of FIG. 26B and the open position of FIG. 26C. Recess 508 has beveled surface 512 on each side facing the hole 510 in the insert **504**. The suture is captured between beveled surface 512 and upper end 514 of hole 510 when insert 504 is in the 25 closed position of FIG. 26B. Insert 504 may be biased toward the closed position by spring portion 516 on insert 504. Spring portion 516 is formed by spiral cut 518 in insert 504. Insert **504** also has pinned connection **520** with main body **502** near the distal end. Pin **522** extends through hole **524** in 30 insert 504 to provide pinned connection 520. Although spring portion 516 is formed integral with insert 504 a separate spring may also be provided similar to other embodiments described herein.

26C by pulling on insert manipulator 524. Manipulator 524 may simply be flexible tether 526, which is pulled to move insert 504 to the unlocked position. When the procedure is completed, tether **526** may be cut and removed. Manipulator **524** provides the user with the ability to adjust suture tension 40 as needed. Bone anchor **500** is used in the same or similar manner as the other apparatuses described herein.

Referring to FIGS. 27A-27B, bone anchor 530 is described. FIG. 27A is a perspective view of an embodiment of a bone anchor. FIG. **27**B is a cross-sectional view of the 45 bone anchor depicted in FIG. 27A. FIG. 27C is an exploded view of the bone anchor depicted in FIG. 27A.

Bone anchor 530 has main body 532 with cleats 531 used to secure the bone anchor to bone although any other feature may be provided to secure bone anchor 530 to bone. The 50 herein. suture is locked with a suture lock 533. Suture lock 533 permits the suture to be advanced in the direction of arrow **556**, but prevents movement in the other direction. The suture extends around bearing surface 534. Bearing surface 534 may be roller **536** although a non-rotating member may also be 55 used. Roller 536 is mounted within hole 538. Suture lock 533 has first locking portion 540 and second locking portion 542, but may include any number of locking portions.

The first and second locking portions 540, 542 are integrally formed as ring clip 550. Ring clip 550 seats within 60 annular recess 552 in main body 532. Suture locks 540, 542 include suture engaging portion 554 extending from ring clip 550. Locks 540, 542 may include an integrally formed living hinge **556**. Living hinge **556** may permit the suture engaging portion 554 to deflect inwardly when suture is pulled in the 65 direction of arrow **556**. Suture lock **533** permits the suture to be pulled in the direction of arrow 556 and prevents the suture

from being moved in the opposite direction. Bone anchor **530** is used in the same manner as bone anchors described herein.

Referring to FIGS. 28A-28D, bone anchor 560 is described. FIG. 28A is a perspective view of an embodiment of bone anchor 560. FIGS. 28B and 28C are cross-sectional views illustrating the use of a release element in conjunction with the bone anchor depicted in FIG. 28A. FIG. 28D is an exploded view of the bone anchor depicted in FIG. 28A. Bone anchor **560** is used in the same manner or similar manner as other bone anchors described herein.

Bone anchor 560 includes suture lock 564. Suture lock 564 allows a suture to be pulled in the direction of arrow **566**, and prevents movement in the other direction. Suture lock 564 includes cam 568 having pinned connection 570 formed by pin 571 rotatable within hole 573 (see FIG. 28D). The suture is locked when the suture is trapped between cam 568 and inner surface **574** of main body **572**.

Bone anchor **560** includes release element **576** for releasing suture lock 564. Release element 576 may be part of ²⁰ introducer **578**. Introducer **578** may be used when advancing bone anchor 560 into bone. Release element 576 extends through a channel of introducer **578**. Release element **576** and main body 572 may be configured (e.g., threaded) to allow the release element to be rotated and advanced to a desired position (e.g., as depicted in FIG. 28B). Release element 576 contacts upper portion of cam 568 and pivots the cam (e.g., as depicted in FIG. 28C). Pivoting the cam permits manipulation of the suture in one or more desired directions.

Further Improvements

Referring to FIG. 29, an alternate non-limiting embodiment of a bone anchor 600 is shown. FIG. 29A depicts an embodiment of a bone anchor having a cam with a suture Insert **504** may be moved to the unlocked position of FIG. 35 positioned between the cam and a surface at the distal end of the bone anchor. FIG. **29**B is a cross-sectional view of the embodiment depicted in FIG. 29A. FIG. 29C is a frontal view of the bone anchor depicted in FIG. 29A. FIG. 29D is an exploded view of the bone anchor and suture depicted in FIG. **29**A.

> It will be apparent to practitioners of ordinary skill in the art that, while the non-limiting embodiment of bone anchor 600 depicted in FIGS. 29A-29D has a substantially flattened profile, such a configuration is merely meant to be illustrative of the many alternate shapes that the presently described bone anchors may take. In different embodiments, bone anchor 600 may be configured to have cross sectional shapes and/or dimensions different from that depicted here, without departing from the spirit or scope of the embodiments set forth

> Bone anchor 600 may include main body 610 with sides 611. Sides 611 may form cavity 612. Sides 611 may entirely or at least partially enclose cavity **612**. The cavity may extend distally along the entire length of the main body, or may optionally extend along only a portion of the length of the main body. Cavity 612 extends to the proximal end of the main body to form opening 613.

> Main body 610 has inner surface 615 positioned at the distal end of end of cavity 612. Inner surface 615 may be formed from the main body at the time of its manufacture, or may be formed by coupling block 616 to the distal end of main body **610** (see FIG. **29**D).

In some embodiments, opening 613 may be fully surrounded at the proximal end of main body 610. In certain embodiments, side surfaces 640 are coupled to main body 610 to enclose opening 613. Side surfaces 640 may be formed from the main body at the time of its manufacture, or may be

formed by coupling retainer 645 to the proximal end of main body 610, as depicted in FIG. 29D.

Referring to FIG. 29A, bone anchor 600 may include cam 650 pivotally positioned in cavity 612. Cam 650 is pivotally coupled to main body 610 using, without limitation, any 5 suitable art-recognized means of forming a rotatable connection. (e.g., a pin). In one non-limiting embodiment, cam 650 may be positioned in cavity 612 such that hole 651 is aligned with holes 652 on opposite sides 611, as depicted in FIG. 29D. Pin 653 may be inserted through the aligned holes to 10 couple cam 650 to main body 610. This connection enables cam 650 to rotate (e.g., pivot) about the axis of pin 653, as shown in FIG. 29B.

In some embodiments, cam 650 may be configured to have an irregular cross sectional shape. FIGS. **29**A-D depicts an 15 embodiment where the cross sectional shape of cam 650 is substantially ovoid (e.g., see particularly FIG. 29B and FIG. 29D). It will apparent to a practitioner of ordinary skill in the art however, that the configuration of the cam presently described embodiment is exemplary only and serves to illus- 20 trate one of the many configurations of cams suitable for use with the subject bone anchors. It will be apparent to ordinary practitioners of the art that cams configured with any cross sectional shape may be substituted for that described herein without departing from the scope of the presently described 25 embodiments.

Coupling cam 650 to main body 610 as described above allows the cam to freely pivot in cavity **612**. In an embodiment, cam 650 may pivot in a first direction (e.g. downward) until outer cam surface 667 comes into contact with inner 30 surface 615 (e.g., as depicted in FIG. 29B). After contact, further rotation of cam 650 in the first direction is blocked. Cam 650 may, however still pivot in the opposite direction (e.g. upward).

that cam surface 667 is biased toward inner surface 615. Any suitable art-recognized means may be used to bias cam surface **667** toward inner surface **615**. Examples of methods to bias a cam include, but are not limited to, coupling the cam to a spring bias assembly, or by forming at least a portion of cam 40 and/or inner surface of the main body from a magnetized material.

Referring to FIG. 29A, one or more coupling members 630 may be disposed on the exterior surface of main body 610. Coupling members may be used to secure bone anchor **600** to 45 an opening in a bone in which the bone anchor is positioned. Main body 610 may include any other suitable feature to secure the bone anchor 600 to bone, such as an expandable portion, without departing from the scope of the invention.

In an embodiment, coupling members 630 may extend 50 radially from the main body. In an embodiment, coupling members 630 may be configured to reversibly engage a bone surface. Typically, coupling members may be formed, at least in part, of a substantially rigid or deformable material. In an embodiment, the coupling members are formed from the 55 main body during the time of its manufacture. In some embodiments, coupling members may be manufactured separately and coupled to the exterior surface of the main body. In some embodiments, the main body may be coupled to the coupling members at the in a point of care setting. The main 60 body may be configured to fit to a variety of coupling members, each having unique features suited to particular applications. A choice of coupling members may be provided to the physician at the point of care and coupled to the main body. Such a system allows the physician to choose the cou- 65 pling member(s) best suited to a particular patient and application (e.g., size, depth and/or width of the bone hole), with**26**

out having to interrupt and prolong the procedure underway in order to choose an alternate bone anchor and prepare it for implantation. The coupling of a main body to coupling members may be by any suitable means generally known in the art. By way of non-limiting examples, a main body may be coupled to coupling members using a snap-locks, screws, adhesives, or any other suitable means described above or generally known in the art. A non-limiting example is depicted in FIG. 29A. A physician may choose clip 620, which includes one or more radially extendable coupling members 630. After the choice is made, the bone anchor is readied for use by coupling clip 620 to main body 610. In an embodiment, a pinned connection may be formed by aligning hole 623 with hole 622 and inserting pin 621 through the aligned holes, as depicted in FIG. 29D. Coupling members 630 extend radially from main body 610.

In an embodiment, a bone anchor may be positioned in an opening in a bone by first retracting the coupling members. Retraction may be accomplished using a device (e.g., an inserter) that is capable of grasping the coupling members and compressing them toward the main body. When the bone anchor is suitably positioned in the bone opening, the inserter releases coupling members, allowing them to move radially outward and engage the surface of the bone opening. Alternatively, the bone anchor may be inserted into a bone opening without retracting the coupling members, and allowing the coupling members to grip the surface of the opening in which the bone anchor is placed.

Suture 660 may be positioned in bone anchor 600 to allow tensioning one or both ends of the suture to optimize positioning of the tissue relative to the bone. Suture **660** includes distal loop portion 665, which is coupled to the tissue, and suture end portions 662a, 662b, which are coupled to bone In some embodiments, cam 650 may be configured such 35 anchor 600. During use, suture end portions 662a and 662b may be tensioned so that the tissue is drawn toward the bone anchor.

Suture end portions 662a, 662b may be coupled to bone anchor 600 by entering through opening 613. Suture end portions 662a, 662b extend toward the distal end of main body 610. To engage cam 650, suture end portions 662a, 662bmay be wrapped around at least a portion of outer surface of cam surface 650. Optionally, cam 650 may be textured on at least a portion of its outer surface. The texturing may allow the cam surface to frictionally grip the suture. The sutures may be wrapped around cam 650 such that the suture contacts at least about 30%, at least about 40%, at least about 50%, at least about 60%, or at least about 70% of the outer surface of cam 650. In an embodiment, suture end portions 662a, 662b may be wrapped around cam 650 in a hairpin configuration as shown in FIGS. 29A and 29B. By wrapping suture end portions 662a, 662b around the lower surface of the cam, the suture ends are positioned in space 666 between outer cam surface 667 and inner surface 615. Wrapping the suture around the cam in a hairpin configuration may maximize contact between the suture length and the outer surface of the cam. Thus, traction between the cam surface and the suture length is enhanced. After being coupled to cam 650, suture end portions 662 and 663 may extend toward the proximal end of main body 610 and exit through opening 613. In an embodiment, side surface 640 may hold suture end portions 662 and 663 in place at opening 613 (See FIG. 29B), allowing the physician greater access to the suture and ease of manipulation of the suture during use.

In an embodiment, a suture puller (not shown) may facilitate threading of the suture ends through the bone anchor described above and shown in FIGS. 29A-D. The suture

puller may be similar in shape and size to the suture coupled to the tissue. In some embodiments, the suture puller is substantially S-shaped.

The suture puller may be threaded through the bone anchor in the same manner as the suture, prior to the positioning of 5 the anchor in a bone opening. The distal end of the suture puller couples to ends of the suture. During use, a loop of suture may pass through a tissue of interest. The end portions of the suture may couple to the distal end of the suture puller. Pulling a proximal end of the suture puller passes the suture puller through the main body of the bone anchor and threads a portion of the suture end through the opening in the main body, around the cam, between the outer cam surface and the inner surface of the main body, and out through the opening in the cavity.

When the suture is coupled to tissue and appropriately threaded through bone anchor 600, the sutured tissue may be drawn toward the bone by individually, or together, tensioning suture end portions 662 and 663 in the direction indicated by arrow 690 shown in FIG. 29B. Tensioning the suture 20 causes cam surface 667 to move (e.g., pivot) away from inner surface 615, allowing movement of suture end portions 662 and 663 in the direction indicated by arrow 690. It will noted however that, due to the configuration of cam surface 667 relative to inner surface 615, after the tension applied to 25 suture end portions 662 and 663 is released, cam surface 667 returns to its position adjacent to inner surface **615**. Tension applied to suture end portions 662 and 663 in the direction indicated by arrow 695 locks the suture in place by compressing end portions 662 and 663 between cam surface 667 and 30 inner surface 615. Thus, movement of a tissue coupled to a suture is allowed only in a desired direction, while slippage or movement of the tissue back to its original position is substantially prevented.

an embodiment of the bone anchor having a suture locking assembly. FIG. 30B is a cross-sectional view of the bone anchor depicted in FIG. 30A. FIG. 30C is a side view of the bone anchor depicted in FIG. 30A. FIG. 30D is an exploded view of the bone anchor depicted in FIG. 30A.

Bone anchor 700 includes insert 710 and main body 715. Insert 710 includes one or more (e.g., a plurality) of flange members 711 (see FIG. 30D). Flange members 711 may extend proximally from insert 710. Cavity 720 is formed between flange members 711. Distal end of cavity 720 45 includes inner surface 719 (see FIG. 30B).

In some embodiments, main body 715 may be configured to couple to insert 710. As depicted in FIG. 30B, main body 715 is configured to accept and encircle flange members 711 and cavity 720. Main body 715 may couple to insert 710 by 50 aligning hole 701 a in main body 715 with holes 701b in flange members 711 (see FIG. 30D). Pin 705 may then be inserted though the aligned holes. Any alternate configurations of insert 710 and main body 715 that allow coupling thereof are possible and their means of coupling, without 55 departing from the spirit and scope of the embodiments provided herein may be used.

Main body 715 may optionally include a plurality of radial coupling members 716. Radial coupling members 716 may secure bone anchor 700 to bone as described herein. Main 60 body 700 may employ any art-recognized means for securing the anchor 700 to bone including, but not limited to, cleats.

Bone anchor 700 may also include locking assembly 740. Locking assembly 740 includes a plurality of locking elements 750. In FIG. 30D, locking elements 750 are depicted as 65 locking rings 750a and 750b. Locking rings 750a and 750b include upper bar 751a and 751b and lower bar 752a and

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752b, respectively. Locking rings 750a and 750b are sized to allow, when the locking rings are positioned parallel to each other, lower bars 752a and 752b to enter cavity 720 as depicted in FIG. 30B. Locking rings 750a and 750b may be positioned parallel to each other when lower bars 752a and 752b are disposed in cavity 720. In some embodiments, the locking rings are substantially parallel to each other. Lower bars 750a and 750b may be individually disposed at various positions or at the same position relative to inner surface 719 of cavity 720. In FIG. 30B, lower bar 752b is positioned adjacent to or in contact with inner surface 719. In some embodiments, lower bar 752a is positioned substantially adjacent to or in direct contact with inner surface 719. In contrast, lower bar 752a is positioned along the longitudinal 15 axis of cavity 720, at a distance farther from inner surface 719 than lower bar 752b. Similarly, upper bar 751b is closer to the opening of cavity 720 than upper bar 751a. Suture gap 760 lies between upper bars 751a and 751b and is sized to accommodate the thickness of a suture. The locking assembly described above may be referred to in some embodiments as a "two bar locking assembly."

In one embodiment, one or more of locking elements 750 may be axially movable in cavity 720. Moving locking element 750 in an axial direction may, in some embodiments, allow the locking elements to interact with each other to either lock or release a suture length positioned in gap 760 by compressing the suture length between upper bars 751a and 751b. In some embodiments, locking element 750 may be moved axially after desired positioning of a sutured tissue (e.g., after fine-tuning placement of the tissue), in order to reversibly lock the suture in place. Axial movement of locking elements 750 may be accomplished using any art-recognized means, including those described in detail above.

Suture 780 is positioned in bone anchor 700 to allow opti-FIGS. 30A-D describe bone anchor 700. FIG. 30A depicts 35 mal positioning of a tissue relative to the bone by individually tensioning the ends of the suture, while substantially inhibiting movement of the suture and tissue coupled thereto in the opposite direction.

In some embodiments, suture **780** is configured to have a distal loop portion 785 and proximal suture end portions 781a and **781***b*. Distal loop portion **785** couples to tissue. Suture end portions 781a and 781b may be treaded through the locking assembly of bone anchor 700, and when tensioned in the direction indicated by arrow 790, draw the tissue toward the bone anchor. In some embodiments, suture end portions **781***a* and **781***b* may be threaded through a two bar locking assembly as depicted in FIGS. 30A and 30B. Loop portion 785 is positioned distally to bone anchor 700, at the tissue. Suture end portions 781a and 781b may couple to locking assembly 740 by passing the suture end portions through the opening of ring 750a and under upper bar 751b. Suture end portions 781a and 781b are wrapped upward around upper bar 751b, passed though suture gap 760 and wrapped upward around upper bar 751a. Suture end portions 781a and 781b are then available for facilitation of positioning of the sutured tissue (see FIG. 30B).

In certain embodiments, a suture puller may facilitate threading of the suture ends through the two bar locking assembly as described above. The suture puller may be similar in shape and size to the suture coupled to the tissue, and may be threaded through the bone anchor in the same manner as the suture, prior to the positioning of the anchor in a bone opening. The distal end of the suture puller couples to suture end portions 781a and 781b. During use, a loop of suture passes through a tissue. The end portions of the suture are coupled to the distal end of the suture puller. Pulling the proximal end of the suture puller in a desired direction (e.g.,

direction 790) passes the suture puller through the locking assembly and threads suture end portions 781a and 781b through ring 750a, under and around upper bar 751b, passed though suture gap 760 and finally wrapped around upper bar 751a.

When the suture is coupled to tissue and appropriately threaded through the locking assembly of the bone anchor, the sutured tissue may be drawn toward the bone by individually or together tensioning suture end portions 781a and 781b in the direction indicated by arrow 790 shown in FIG. 30B. 10 Tensioning the suture ends thus allows the threaded suture to move through the locking assembly in direction 790, thus drawing tissue toward the bone. It will noted however that, due to the configuration of the two bar locking assembly relative to the threaded suture, movement or slippage of the 15 tissue in an opposite direction is substantially inhibited. Tensioning the suture distally, in the direction indicated by arrow 795, causes the suture to apply an upward force to upper bar 751b, causing upper bar 751b and 751a to interact such that the suture length positioned in gap 760 is compressed 20 between the upper bars, thus substantially locking the suture in place.

Modular Design

Bone anchor **600** described certain embodiments where the main body is configured to be used with a variety of different 25 coupling members, each having features suited to particular applications. It will be readily appreciated by ordinary practitioners of the art however, that this feature is not limited to the embodiments of bone anchor **600**. Neither is this feature meant to be limited to the coupling of an internal portion to an 30 external portion. In the contrary, components of the bone anchor assemblies described above are designed with the feature of modularity in mind. The ability to mix-and-match different features of an internal portion of a bone anchor assembly with a wide variety of features of external portions 35 of the bone anchor is intended to be applied, without limitation, to all the embodiments described herein.

Incorporating the feature of modularity into the bone anchor assembly design parameters provides the following advantages: (a) maximized versatility in surgical applications 40 without having to redesign bone anchor suited to such applications; (b) maintaining flexibility of the surgical procedure at the point-of-care; (c) full interchangeability of any component with any other component; (d) adjustability of each bone anchor component independent of the choice or position of 45 other bone anchor components being used in a single surgical application; (e) allows the surgeon to tailor the assembly to the individual anatomy of the patient even in the face of a revision of the surgical procedure that might otherwise damage the bone or tissue; and (f) the use of all styles and sizes of 50 interior and exterior components. The feature of modularity allows the physician to dedicate his or her full attention the procedure at hand, improving the prognosis and healing of the patient.

Securing a bone anchor member within a hole of a bone 55 may be employed as previously described or using generally known bone securing techniques. For example, cleated members 42 of FIG. 2A, may be used means for securing the bone anchors. Other alternative means for securing may be used in conjunction with the apparatus and methods of the present 60 invention. As an example, the bone anchor member may employ one or more radially expandable members that extend into the surrounding bone.

Further, while some of the embodiments of the present invention describe use of a bone anchor member only, and 65 other embodiments describe use of a bone anchor member and a plug portion, many of these features may be inter-

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changed. It will be apparent to one skilled in the art that many embodiments depicting a bone anchor member only may be performed using a bone anchor member and plug portion, and vice versa.

Also, for those embodiments described above having a bone anchor member and a plug portion, it will be apparent to those skilled in the art that the suture ends may be tensioned either before or after the plug portion is inserted into the bore of the bone anchor member.

It will also be apparent to one skilled in the art that the plug portion may be securely disposed within the bore of the bone anchor member using various means not specifically disclosed herein. For example, after the plug portion is inserted into the bore of the bone anchor member, an adhesive, for example, cyanoacrylate, epoxy, bone cement and so forth, may be delivered to affix the plug portion to the bone anchor member. Alternatively, an exterior surface of the plug portion may be coated with a biocompatible adhesive that affixes to the bone anchor member after the plug portion is inserted into the bore of the bone anchor member. In some embodiments, heat may be applied to fuse the plug portion to the bone anchor member. It will be apparent to one skilled in the art that still further means for securing the plug portion to the bone anchor member may be employed.

It should be understood that multiple bone anchor members, or multiple bone anchor members coupled to respective plug portions may be used. One or more sutures may be coupled between a desired tissue region and the bone anchor member or plug portion. If multiple sutures and bone anchor members are employed, enhanced sequential tensioning of the tissue may be achieved.

Finally, while the above-described embodiments reference use of apparatus and methods for facilitating attachment of tissue to bone, it will be apparent to one skilled in the art that such apparatus and methods may also be used to secure tissue-to-tissue and bone-to-bone.

While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the spirit and scope of the invention. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

In this patent, certain U.S. patents, U.S. patent applications, and other materials (e.g., articles) have been incorporated by reference. The text of such U.S. patents, U.S. patent applications, and other materials is, however, only incorporated by reference to the extent that no conflict exists between such text and the other statements and drawings set forth herein. In the event of such conflict, then any such conflicting text in such incorporated by reference U.S. patents, U.S. patent applications, and other materials is specifically not incorporated by reference in this patent.

Further modifications and alternative embodiments of various aspects of the invention may be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as the presently preferred embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description to the invention. Changes may be made in the elements described herein with-

out departing from the spirit and scope of the invention as described in the following claims. In addition, it is to be understood that features described herein independently may, in certain embodiments, be combined.

What is claimed is:

- 1. A bone anchor system for coupling tissue to bone, the bone anchor system comprising:
 - a main body configured to be placed in a bone, the main body comprising a proximal end, a distal end, and a cavity, the cavity comprising a first opening at or near the proximal end; and
 - a locking assembly at least partially disposed in the cavity, the locking assembly comprising:
 - a first locking element;
 - a second locking element interacting with the first locking element, the first and second locking elements movable with respect to the cavity; and
 - a filament extending along a suture path through a second opening in the first locking element in a direction toward the second locking element, through a suture gap between the first locking element and the second locking element, around the second locking element, through a third opening in the second locking element, and back through the second opening, wherein the first and second locking elements are positionable with respect to each other such that the filament is moveable along the suture path in a first direction and inhibited from moving in a second direction.
- 2. The bone anchor system of claim 1, wherein the cavity extends along a longitudinal axis of the main body.
- 3. The bone anchor system of claim 1, further comprising one or more coupling members disposed on a surface of the main body, wherein the one or more coupling members are configured to substantially inhibit the main body from moving out of the bone.
- 4. The bone anchor system of claim 1, further comprising an insert coupled to the main body, wherein the cavity is at least partially defined by at least a portion of the main body and at least a portion of the insert.
- 5. The bone anchor system of claim 1, wherein the first and second locking elements are axially movable with respect to each other.
- 6. The bone anchor system of claim 1, wherein each of the first and second locking elements comprises a proximal portion and a distal portion, and wherein the distal portions are disposed in the cavity.
- 7. The bone anchor system of claim 1, wherein the first and second locking elements are substantially parallel to each other.
- 8. The bone anchor system of claim 1 wherein the first locking element comprises a first locking ring, and wherein the second locking element comprises a second locking ring.
- 9. The bone anchor system of claim 8, wherein each of the first and second locking rings comprises an upper bar located along the suture path and a lower bar disposed at least partially in the cavity.
- 10. The bone anchor system of claim 1, wherein the filament is a suture puller, wherein the suture puller is configured to thread at least a portion of a suture through the locking assembly.
- 11. The bone anchor system of claim 1, further comprising an inserter, the inserter being configured to be reversibly

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coupled to the main body, wherein the inserter is configured to position the main body in a fourth opening in the bone.

- 12. The bone anchor system of claim 1 wherein the first direction comprises a portion of the suture path extending from the second locking element, through the suture gap, and toward the first locking element.
- 13. The bone anchor system of claim 1 wherein the locking assembly comprises a reversible locking assembly.
- 14. The bone anchor system of claim 1 wherein the second direction comprises a portion of the suture path extending from the first locking element, through the suture gap, and toward the second locking element.
 - 15. The bone anchor system of claim 1 wherein the locking assembly comprises a two bar locking assembly.
 - 16. The bone anchor system of claim 1 further comprising an insert coupled to the main body, wherein the locking assembly is part of the insert.
 - 17. The bone anchor system of claim 1, wherein the filament is a suture.
 - 18. The bone anchor system of claim 17, wherein movement of at least one of the first and second locking elements in an axial direction with respect to another of the first and second locking elements allows or inhibits movement of the suture.
- 25 19. The bone anchor system of claim 17, wherein the suture comprises a distal loop portion and two proximal end portions, wherein at least one of the two proximal end portions is coupled to the locking assembly such that tensioning the at least one of the two proximal end portions in the first direction moves the suture in the first direction, and tensioning the at least one of the two proximal end portions in the second direction engages the locking assembly to inhibit movement of the suture.
- 20. The bone anchor system of claim 17 wherein movement of the suture in the first direction increases the suture gap.
- 21. The bone anchor system of claim 17 wherein movement of the suture in the first direction displaces the first locking element away from the proximal end of the main body to permit suture movement in the first direction.
 - 22. The bone anchor system of claim 17 wherein movement of the second locking element toward the proximal end of the main body permits suture movement in both the first and second directions.
 - 23. The bone anchor system of claim 17 wherein movement of the suture in the second direction decreases the suture gap to inhibit suture movement in the second direction.
- 24. The bone anchor system of claim 17 wherein movement of the suture in the second direction displaces the second locking element away from the proximal end of the main body to inhibit suture movement in the second direction.
- 25. The bone anchor system of claim 17 wherein movement of the suture in the second direction compresses the suture between the first and second locking elements to inhibit suture movement in the second direction.
 - 26. The bone anchor system of claim 17 wherein movement of the suture in the first direction creates tension on the suture in the second direction.
 - 27. The bone anchor system of claim 17 wherein the first and second locking elements are axially movable with respect to each other to compress the suture in the suture gap.

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